TERMS OF REFERENCE AND PROFILE FOR MEMBERS OF GROUPS OF EXPERTS AND WORKING PARTIES

The terms of reference and profiles shown below have been drafted by the Presidium to aid national authorities when making proposals for appointment. In addition to the profile described, national authorities should also ensure that the experts proposed are available to attend meetings and are prepared to draft and/or verify monographs and general chapters and when required in the profile, have access to a laboratory for experimental verifications.

Each group of experts and working party will advise the Commission and other groups of experts and working parties where relevant, according to their expertise and contribute to the maintenance of the relevant technical guide where appropriate.

The chairs of the following groups are members of the PCM working party: Groups 6, 7, 9, 10A/B/C/D, 11, 13H, 14, 17, P4 and MG WP. The chairs of the other groups of experts and working parties may be invited on an ad hoc basis, depending on the agenda. The Chair of the Ph. Eur. Commission is chairing the PCM and ROP working parties.

In the context of this document, the term "regulatory authority" encompasses OMCLs, licensing authorities, NPAs and/or inspectorates.

Group of Experts No. 1 (Microbiology)

Terms of reference

- Drafting and revision of general chapters in the field of microbiology
- Advising the Commission on questions related to microbiological quality, including quality attributes in monographs drafted by other groups of experts and working parties
- International harmonisation of general chapters in the field of microbiology
- Drafting and revision of general chapters in the field of alternative microbiological methods (the so called “rapid methods”)
- Assessment of proposed examples in view of their inclusion in document: “*Examples of validation protocols for alternative microbiological methods according to chapter 5.1.6*”, to be published on the EDQM website.

Profile for experts

- Current expertise in microbiological analytical methods, related to quality control of active substances, excipients and medicinal products and in development of control methods
- Several years of experience in one or more of the following fields
    - Microbiological quality control in a pharmaceutical manufacturing setting, in a hospital environment or in an independent testing laboratory
    - Market surveillance of microbiological quality in a regulatory authority
    - Assessment of the relevant parts of applications for marketing authorisation
    - Development of microbiological control methods in a research and development environment

Profile for ad-hoc specialists on alternative microbiological methods (please indicate this field of expertise on the nomination form, if applicable)

- Current expertise in microbiological analytical methods, related to quality control of active substances, excipients and medicinal products and in development of control methods
- Several years of experience in one or more of the following fields:
    - Validation of alternative microbiological methods in a pharmaceutical manufacturing setting, in a hospital environment or in an independent testing laboratory
    - Market surveillance of microbiological quality in a regulatory authority using alternative microbiological methods
    - Assessment of the relevant parts of applications for marketing authorisation
    - Development of alternative microbiological control methods in a research and development environment

Group of Experts No. 6 (Biological and Biotechnological products)

Terms of reference

- Drafting and revision of texts in the field of biological products, biotechnological products, including glycoproteins, and synthetic peptides
- International harmonisation of general chapters in the field of biological products

Profile for experts

- Current expertise in quality control of biological products, biotechnological products (including glycoproteins), peptides
- Access to laboratory facilities for verification and validation of analytical procedures proposed for inclusion in monographs, **Essential**: Active involvement in laboratory verification of analytical procedures and drafting of texts
- Several years of experience in one or more of the following fields:
    - Quality control of biological products, biotechnological products, including glycoproteins or of peptides in a pharmaceutical manufacturing setting
    - Quality control in a regulatory authority
    - Quality control of biological or biotechnological products, including glycoproteins, or of peptides in an independent testing laboratory
    - Development of analytical procedures for control of biological or biotechnological products, including glycoproteins or of peptides in a research and development environment
    - Analytical procedure development and verification in a regulatory authority
    - Assessment of the relevant parts of application for marketing authorisation of biological and biotechnological products within a medicines agency

Group of Experts No. 6B (Human Plasma and Plasma Products)

Terms of reference

- Drafting and revision of texts in the field of blood products

Profile for experts

- Current expertise in the field of blood products, notably related to their quality control and development of analytical procedures for control of these products
- Access to laboratory facilities for verification and validation of analytical procedures proposed for inclusion in monographs, **Essential**: Active involvement in laboratory verification of analytical procedures and drafting of texts
- Several years of experience in one or more of the following fields:
    - Quality control of blood products in a pharmaceutical or bulk manufacturing setting
    - Batch release or market surveillance of Human Blood, Plasma and Plasma Products in a regulatory authority
    - Assessment of the relevant parts of applications for marketing authorisation within a medicines agency
    - Quality control of blood products in an independent testing laboratory
    - Analytical procedure development and verification in a regulatory authority
    - Development of analytical procedures for control of Human Plasma and Plasma Products in a research and development environment

Group of Experts No. 7 (Antibiotics)

Terms of reference

- Drafting and revision of texts in the field of antibiotic active substances
- Provision of expertise in the field of antibiotics to Group 17 where relevant

Profile for experts

- Current expertise in the fields of antibiotics
- Access to laboratory facilities for verification and validation of analytical procedures proposed for inclusion in monographs, **Essential**: Active involvement in laboratory verification of analytical procedures and drafting of texts
- Several years of experience in one or more of the following fields:
    - Quality control of antibiotics in a pharmaceutical manufacturing setting
    - Quality control of antibiotics in a bulk manufacturing setting
    - Quality control of antibiotics in a regulatory authority
    - Assessment of the relevant parts of applications for marketing authorisation within a medicines agency
    - Quality control of antibiotics in an independent testing laboratory
    - Development of analytical procedures for control of antibiotics in a research and development environment
    - Analytical procedure development and verification in a regulatory authority

Group of experts No. 9 (Inorganic Chemistry)

Terms of reference

- Drafting and revision of monographs in the field of inorganic substances
- International harmonisation of monographs

Profile for experts

- Current expertise in pharmaceutical analytical procedures, related to quality control of inorganic substances and in development of such analytical procedures
- Access to laboratory facilities for verification and validation of analytical procedures proposed for inclusion in monographs, for example ICP and/or AAS. **Essential**: Active involvement in laboratory verification of analytical procedures and drafting of texts.
- Several years of experience in one or more of the following fields:
    - Quality control of inorganic substances in a pharmaceutical or bulk manufacturing setting
    - Market surveillance of quality in a regulatory authority
    - Pharmaceutical quality control in an independent testing laboratory
    - Development of analytical procedures for control of inorganic substances in a research and development environment
    - Analytical procedure development and verification in a regulatory authority

Group of Experts No. 9G (Medicinal Gases)

Terms of reference

- Drafting and revision of texts in the field of medicinal gases

Profile for experts

- Current expertise in the field of medicinal gases
- Access to laboratory facilities for verification and validation of analytical procedures proposed for inclusion in monographs, **Essential**: Active involvement in laboratory verification of analytical procedures and drafting of texts
- Several years of experience in one or more of the following fields:
    - Quality control of medicinal gases in a pharmaceutical manufacturing, hospital or industrial setting
    - Quality control in a regulatory authority
    - Development of analytical procedures for control of medicinal gases in a research and development environment

Group of Experts No. 10A/B/C/D (Organic chemistry – synthetic and semi-synthetic substances)

Terms of reference

- Drafting and revision of monographs in the field of synthetic and semi-synthetic organic substances
- If needed, provide expertise in the field of organic chemistry to Group 17

Profile for experts

- Current expertise in pharmaceutical analytical procedures, related to quality control of synthetic and semi-synthetic organic substances and in development of such analytical procedures
- Access to laboratory facilities for verification and validation of analytical procedures proposed for inclusion in monographs, **Essential**: Active involvement in laboratory verification of analytical procedures and drafting of texts.
- Several years of experience in one or more of the following fields:
    - Quality control in a pharmaceutical manufacturing setting
    - Quality control of synthetic and semi-synthetic organic products in a bulk manufacturing setting
    - Market surveillance of quality in a regulatory authority
    - Pharmaceutical quality control of synthetic and semi-synthetic organic substances, in an independent testing laboratory
    - Development of analytical procedures for control of synthetic and semi-synthetic organic substances in a research and development environment
    - Group 10D: development of analytical procedures for amino-acids
    - Analytical procedure development and verification in a regulatory authority

Group of Experts No. 11 (Organic chemistry – natural, semi-synthetic and synthetic substances)

Terms of reference

- Drafting and revision of monographs in the field of natural, semi-synthetic and synthetic organic substances
- Provision of expertise in the field of organic chemistry to the Group 17 where relevant

Profile for experts

- Current expertise in pharmaceutical analytical procedures, related to quality control of natural, semi-synthetic and synthetic organic substances, and in development of such analytical procedures

- Access to laboratory facilities for verification and validation of analytical procedures proposed for inclusion in monographs, **Essential**: Active involvement in laboratory verification of analytical procedures and drafting of texts.
- Several years of experience in one or more of the following fields:
    - Quality control in a pharmaceutical manufacturing setting
    - Quality control of natural, semi-synthetic and synthetic organic substances in a bulk manufacturing setting
    - Market surveillance of quality in a regulatory authority
    - Pharmaceutical quality control in an independent testing laboratory
    - Development of analytical procedures for control of natural, semi-synthetic and synthetic organic substances in a research and development environment
    - Analytical procedure development and verification in a regulatory authority

Group of Experts No. 12 (Dosage forms and pharmaceutical technical procedures)

Terms of reference

- Drafting and revision of dosage form monographs and pharmaceutical technical procedures
- Maintenance of dosage form related International Harmonisation topics such as:
    - uniformity of dosage units
    - dissolution
    - disintegration
- Particulate contamination: visible and sub-visible particles
- Provision of expertise in the field of pharmaceutical technology to other groups where relevant

Profile for experts

- Current expertise in pharmaceutical development and analytical procedures used for in-process control and end product testing of pharmaceutical preparations, in the relevant specialities defined in the terms of reference
- Several years of experience in one or more of the following fields:
    - Development and quality control of pharmaceutical preparations in an industrial setting
    - Assessment of the relevant parts of applications for marketing authorisation within a medicines agency
    - Development of analytical procedures for testing of pharmaceutical preparations in a research and development environment
    - Analytical procedure development and verification in a regulatory authority

Group of Experts No. 13A/B (Herbal Drugs and Herbal Drug Preparations)

Terms of reference

- Drafting and revision of texts in the field of herbal drugs and herbal drug preparations

Profile for experts

- Current expertise in pharmaceutical analytical procedures, related to quality control of herbal drugs and herbal drug preparations and in development of such analytical procedures
- Access to laboratory facilities for verification and validation of analytical procedures proposed for inclusion in monographs, **Essential**: Active involvement in laboratory verification of analytical procedures and drafting of texts.

- Several years of experience in one or more of the following fields:
    - Quality control of herbal drugs and herbal drug preparations in a pharmaceutical manufacturing or bulk manufacturing setting
    - Market surveillance of quality of herbals in a regulatory authority
    - Assessment of the relevant parts of applications for marketing authorisation of herbal medicinal products within a medicines agency
    - Pharmaceutical quality control of herbal drugs and herbal drug preparations in an independent testing laboratory
    - Development of analytical procedures for control of herbal drugs in a research and development environment
    - Analytical procedure development and verification in a regulatory authority

Group of Experts No. 13H (Fatty oils and derivatives, polymers)

Terms of reference

- Drafting and revision of texts in the field of:
    - surfactants
    - fatty oils, fats and waxes
    - fatty acids, fatty alcohols and their esters/ethers
    - macrogols, macrogol derivatives and other polymers (e.g. carbomers)
    - paraffins
- International Harmonisation of the relevant monographs

Profile for experts

- Current expertise in pharmaceutical analytical procedures, related to quality control in the relevant specialities defined in the terms of reference
- Member of a regulatory authority, universities or the pharmaceutical/chemical industries
- Access to laboratory facilities for verification and validation of analytical procedures proposed for inclusion in monographs, **Essential**: Active involvement in laboratory verification of analytical procedures and drafting of texts
- Several years of experience in one or more of the following fields:
    - Quality control in a pharmaceutical manufacturing setting
    - Quality control of fats etc. in a bulk manufacturing setting
    - Market surveillance of quality in a regulatory authority
    - Pharmaceutical quality control of fats etc. in an independent testing laboratory
    - Development of analytical procedures for control of fats etc. in a research and development environment
    - Analytical procedure development and verification in a regulatory authority

Group of Experts No. 14 (Radiopharmaceutical Preparations)

Terms of reference

- Drafting and revision of texts in the field of radiopharmaceutical preparations

Profile for experts

- Current expertise in pharmaceutical analytical procedures, related to quality control of radiopharmaceutical preparations and in development of such analytical procedures

- Access to laboratory facilities for verification and validation of analytical procedures proposed for inclusion in monographs, **Essential**: Active involvement in laboratory verification of analytical procedures and drafting of texts
- Several years of experience in one or more of the following fields:
    - Quality control of radiopharmaceutical preparations in a pharmaceutical manufacturing setting or in a hospital
    - Market surveillance of quality of radiopharmaceutical preparations in a regulatory authority
    - Assessment of the relevant parts of applications for marketing authorisation within a medicines agency
    - Pharmaceutical quality control of radiopharmaceutical preparations in an independent testing laboratory
    - Analytical procedure development and verification in a regulatory authority

Group of Experts No. 15 (Human Vaccines and Sera)

Terms of reference

- Drafting and revision of texts in the field of vaccines and sera for human use
- Drafting and revision of monographs in the field of botulinum toxins

Profile for experts

- Current expertise in analytical procedures, related to quality control of vaccines and sera for human use and in development of such analytical procedures
- Several years of experience in one or more of the following fields:
    - Quality control of vaccines and sera for human use in a pharmaceutical manufacturing setting
    - Batch release and market surveillance of quality of vaccines and sera for human use in a regulatory authority
    - Assessment of the relevant parts of applications for marketing authorisation within a medicines agency
    - Quality control of vaccines and sera for human use in an independent testing laboratory

Profile for botulinum toxins ad hoc specialists (please indicate this field of expertise on the nomination form, if applicable)

- Current expertise in analytical procedures for the control of botulinum toxins and in development of such analytical procedures
- Several years of experience in one or more of the following fields:
    - Quality control of botulinum toxins in a pharmaceutical manufacturing setting
    - Batch release or market surveillance of quality of botulinum toxins in a regulatory authority
    - Assessment of the relevant parts of applications for marketing authorisation within a medicines agency
    - Pharmaceutical quality control of botulinum toxins in an independent testing laboratory
    - Development of analytical procedures for control of botulinum toxins in a research and development environment

Group of Experts No. 15V (Veterinary Vaccines and Sera)

Terms of reference

- Drafting and revision of texts in the field of immunological veterinary medicinal products (IVMP)

Profile for experts

- Current expertise in suitable standards for IVMP, in analytical procedures related to quality control of these products and in development of such analytical procedures
- Several years of experience in one or more of the following fields:
    - Quality control of IVMP in a regulatory authority
    - Assessment of the relevant parts of applications for marketing authorisation within a medicines agency
    - Batch release and market surveillance of quality in a regulatory authority
    - Development of analytical procedures for control of IVMP in a research and development environment
- Industry representatives are normally not appointed to Group of Experts No. 15V. They may be invited to contribute to elaboration of texts during hearings organised on a case-by-case basis by the Secretariat.

Group of Experts No. 16 (Plastic materials, plastic containers and closures)

Terms of reference

- Drafting and revision of texts in the field of plastic materials, plastic containers and closures

Profile for experts

- Current expertise in the fields covered by the terms of reference
- Access to laboratory facilities for verification and validation of analytical procedures proposed for inclusion in texts, **Essential**: Active involvement in laboratory verification of analytical procedures and drafting of texts
- Several years of experience in one or more of the following fields:
    - Quality control of plastic materials, plastic containers and closures
      - in a pharmaceutical manufacturing setting,
      - in a regulatory authority or
      - in an independent testing laboratory
    - Assessment of the relevant parts of applications for marketing authorisation within a medicines agency
    - Analytical procedure development and verification in a regulatory authority

Group of Experts 17 (Medicinal products containing chemically defined active substances)

Terms of reference

- Drafting and revision of monographs on medicinal products containing chemically defined active substances
- Drafting of monographs on active substances contained in these medicinal products if the monographs are being elaborated in parallel and if deemed appropriate;
- Drafting and maintenance of the technical guide for the elaboration of monographs on medicinal products containing chemically defined active substances
- Provision of expertise to other groups (such as Group P4) where relevant

Profile for experts

- Current expertise in pharmaceutical analytical procedures, related to quality control of medicinal products containing chemically defined active substances and in development of such analytical procedures
- Access to laboratory facilities for verification and validation of analytical procedures proposed for inclusion in monographs, **Essential**: Active involvement in laboratory verification of analytical procedures and drafting of texts.
- Several years of experience in one or more of the following fields:
    - Development and verification of analytical procedures
    - Quality control or development of medicinal products containing chemically defined active substances
    - Market surveillance testing
    - Assessment of the relevant parts of applications for marketing authorisation within a medicines agency

Group of Experts P4

Terms of reference

- Drafting and revision of monographs in the field of single-source active substances, excipients and medicinal products with chemically defined active substances

Profile for experts

- Current expertise in pharmaceutical analytical procedures, related to quality control of active substances, excipients and medicinal products (with chemically defined active substances), and in development of such analytical procedures
- Access to laboratory facilities for verification and validation of analytical procedures proposed for inclusion in monographs or access to licensing files, **Essential**: Active involvement in laboratory verification of analytical procedures and drafting of texts.
- Several years of experience in one or more of the following fields:
    - Assessment of the relevant parts of applications for marketing authorisation
    - Market surveillance studies in a regulatory authority
    - Analytical procedure development and verification in a regulatory authority
- Group P4 is restricted to regulators from Ph. Eur. Member states however industry representatives may be invited to contribute by submission of data and interaction with the group via the Secretariat

ALG Working Party (Allergens)

Terms of reference

- Drafting and revision of texts in the field of allergen products

Profile for experts

- Current expertise in pharmaceutical analytical procedures, related to quality control of allergens and in development of such analytical procedures
- Several years of experience in one or more of the following fields:
    - Quality control of allergen products in a pharmaceutical manufacturing setting
    - Market surveillance of quality of allergen products in a regulatory authority
    - Assessment of the relevant parts of applications for marketing authorisation within a medicines agency

- Pharmaceutical quality control of allergen products in an independent testing laboratory
- Development of analytical procedures for control of allergens in a research and development environment

ALU Working Party (Aluminium in parenteral nutrition solutions)

Terms of reference

- Drafting of general chapter on aluminium in parenteral nutrition solutions

Profile for experts

- Current expertise in parenteral nutrition solutions, notably related to quality and toxicological assessment of aluminium content, or in aluminium in parenteral preparations,
- Several years of experience in one or more of the following fields
  - Quality control of parenteral nutrition solutions and/or parenteral preparations
  - Assessment of the relevant parts of applications for marketing authorisation
  - Development and verification of analytical procedures for control of aluminium in parenteral preparations and/or parenteral nutrition solutions
  - Market surveillance of quality of parenteral preparations and/or parenteral nutrition solutions in a regulatory authority
  - Preparation and administration of parenteral nutrition solutions or of parenteral preparations in a clinical setting

AQbD Working Party (Analytical quality by design)

Terms of reference

- Assess the feasibility and impact of incorporating analytical procedures developed using the concepts of analytical quality by design (aQbD) in Ph. Eur. monographs.
- Advise the Commission and expert groups on appropriate elaboration/revision strategies for incorporating such analytical procedures in monographs.
- Identify verification and revision approaches for analytical procedures developed using aQbD.
- Co-operation and consultation with other groups of experts and working parties in charge of the elaboration and revision of monographs, where relevant.

Profile for experts

- Current expertise in the development of analytical procedures for the assessment of the quality of active substances and medicinal products
- Knowledge of pharmacopoeial monograph development
- Several years of experience in one or more of the following fields:
  - Development, validation and verification of analytical procedures, if possible applying aQbD concepts
  - Market surveillance testing
  - Assessment of the relevant parts of applications for marketing authorisation within a medicines agency, if possible with experience of assessing applications that used aQbD concept.

BACT Working Party (Bacteriophages)

Terms of reference

- To elaborate the general chapter 'Phage therapy active substances and medicinal products for human and veterinary use'.

Profile for experts

- Current expertise in analytical procedures related to quality control of bacteriophages and in development of such analytical procedures
- Several years of experience in one or more of the following fields:
    - Quality control of bacteriophages in a manufacturing setting
    - Preparation and administration of bacteriophages manufactured in a non-industrial way but of a quality compatible with clinical use (compassionate access)
    - Development of bacteriophages for clinical use
    - Analytical procedure development and verification in a regulatory authority

BET Working Party (Bacterial Endotoxin Test)

Terms of reference

- Drafting and revision of general chapters in the field of bacterial endotoxins
- Advising the Commission and expert groups on appropriate analytical procedures for the detection of bacterial endotoxins or pyrogens in substances for pharmaceutical use or pharmaceutical preparations.
- Drafting and revision of general chapters in the field of the monocyte activation tests (MAT)
- International Harmonisation of the relevant texts

Profile for experts

- Current expertise in practical application of the bacterial endotoxin test and/or MAT
- Several years of experience in one or more of the following fields:
    - Quality control of parenteral preparations, active substances and/or excipients in a pharmaceutical manufacturing setting
    - Market surveillance of quality in a regulatory authority
    - Pharmaceutical quality control in an independent testing laboratory
    - Development of analytical procedures for bacterial endotoxin testing and/or MAT in a research and development environment
    - Analytical procedure development and verification in a regulatory authority
- Access to laboratory facilities for verification and validation of analytical procedures proposed for inclusion in monographs

BSR Working Party (Bovine serum)

Terms of reference

- Maintenance of the monograph *Bovine serum* (2262)
- Drafting and revision of other texts pertaining to bovine sera as appropriate

Profile for experts

- Current expertise in analytical procedures related to quality control of bovine sera and in development of such analytical procedures

- Several years of experience in one or more of the following fields:
    - Quality control of bovine serum in a pharmaceutical manufacturing setting
    - Market surveillance of quality in a regulatory authority
    - Assessment of the relevant parts of applications for marketing authorisation within a medicines agency
    - Pharmaceutical quality control in an independent testing laboratory
    - Development of analytical procedures for control of bovine serum in a research and development environment

CE Working Party (Capillary Electrophoresis)

Terms of reference

- Revision of the chapter *2.2.47 Capillary electrophoresis*
- Advising the Commission on questions related to capillary electrophoresis in monographs drafted by other groups of experts and working parties
- International Harmonisation of the relevant texts

Profile for experts

- Current expertise in *Capillary electrophoresis* techniques
- Several years of experience in the following fields:
    - Quality control of active substances, excipients and medicinal products, using capillary electrophoresis techniques, in a pharmaceutical manufacturing setting, in a regulatory authority or in any other testing laboratory
    - Development of analytical procedures using capillary electrophoresis for control of active substances, excipients and medicinal products in a research and development environment or at university
    - Access to laboratory facilities for verification and validation of analytical procedures proposed for inclusion in monographs **Essential**: Active involvement in laboratory verification of analytical procedures and drafting of texts

CEL Working Party (Cellulose)

Terms of reference

- Drafting and revision of monographs on cellulose and cellulose derivatives
- International harmonisation of monographs on cellulose and cellulose derivatives

Profile for experts

- Current expertise in analytical procedures for cellulose and cellulose derivatives and in development of such analytical procedures
- Access to laboratory facilities for verification and validation of analytical procedures proposed for inclusion in monographs, **Essential**: Active involvement in laboratory verification of analytical procedures and drafting of texts.
- Several years of experience in one or more of the following fields:
    - Quality control of cellulose and cellulose derivatives in a pharmaceutical or other industrial manufacturing setting
    - Market surveillance of quality of cellulose and cellulose derivatives in a regulatory authority
    - Quality control of cellulose and cellulose derivatives in a regulatory authority

- Development of analytical procedures for control of cellulose and cellulose derivatives in a research and development environment
- Analytical procedure development and verification in a regulatory authority

COL Working Party (Colour determination)

Terms of reference

- Drafting and revision of monographs and texts in the field of instrumental determination of colour (PDG item Q-07)
- Establishing correlation between measurement using Ph. Eur. Chapter 2.2.2 and the tristimulus type instruments

Profile for experts

Several years of experience in one or more of the following fields:

- Users: Expertise in the use of tristimulus-type of colour measuring instruments in the field of pharmaceutical development, quality control of pharmaceuticals, food, cosmetics or drinking water
- Instrument suppliers: Personnel involved in user-support for practical application of tristimulus-type instruments in the field of pharmaceutical development, quality control of pharmaceuticals, food, cosmetics or drinking water
- Experience in research or university teaching related to instrumental colour determination of liquids

CRB Working Party (Carbohydrates)

Terms of reference

- Drafting and revision of monographs in the field of carbohydrates
- International harmonisation of monographs

Profile for experts

- Current expertise in pharmaceutical analytical procedures, related to quality control of carbohydrates and in development of such analytical procedures
- Access to laboratory facilities for verification and validation of analytical procedures proposed for inclusion in monographs, **Essential**: Active involvement in laboratory verification of analytical procedures and drafting of texts.
- Several years of experience in one or more of the following fields:
  - Quality control in a pharmaceutical or bulk manufacturing setting
  - Market surveillance of quality in a regulatory authority
  - Pharmaceutical quality control in an independent testing laboratory
  - Development of analytical procedures for control of carbohydrates in a research and development environment
  - Analytical procedure development and verification in a regulatory authority

CST Working Party (Chromatographic separation techniques)

Terms of reference

- Revision of chapters on chromatographic separation (e.g. 2.2.28, 2.2.29, 2.2.30, 2.2.46)
- Advising the Commission on questions related to chromatographic separation techniques in monographs drafted by other groups of experts and working parties

- Co-operation with other groups of experts and working parties which use chromatographic separation techniques where relevant

Profile for experts

- Current expertise in chromatographic separation techniques
- Several years of experience in one or more of the following fields:
    - Chromatographic quality control of active substances and/or excipients in a pharmaceutical manufacturing setting
    - Development of chromatographic analytical procedures for control of active substances, excipients and medicinal products in a research and development environment
    - Market surveillance of quality in a regulatory authority
    - Pharmaceutical quality control in an independent testing laboratory

CTP Working Party (Cell Therapy Products)

Terms of reference

- Drafting and revision of texts in the field of cell-based preparations
- Maintaining regular exchanges to ensure coordination of approaches with the GTP Working Party in relevant areas

Profile for experts

- Current expertise in analytical procedures related to the development and quality control of cell therapy products and/or tissue-engineered products and/or to the quality control of tissues for human use
- Several years of experience in one or more of the following fields:
    - Development of cell therapy products and/or tissue-engineered products
    - Quality control of cell therapy products and/or tissue-engineered products in a pharmaceutical manufacturing setting or in a hospital environment and/or microbiological control of tissues and organs used for human transplantation
    - Assessment of applications for marketing authorisation of cell therapy and/or tissue-engineered products
    - Market surveillance of the quality of cell therapy products, tissue-engineered products and/or tissues and organs used for human transplantation in a regulatory authority
    - Pharmaceutical quality control in an independent testing laboratory
    - Development of analytical procedures (e.g. microbiological procedures) to control cell therapy products and/or tissue-engineered products and/or tissues and organs used for human transplantation in a research and development environment

DIA Working party (Dialysis)

Terms of reference

- Drafting and revision of texts in the field of preparations for dialysis

Profile for experts

- Current expertise in the field of preparations for dialysis
- Access to laboratory facilities for verification and validation of analytical procedures proposed for inclusion in monographs
- Several years of experience in one or more of the following fields:

- Manufacture and/or quality control of preparations for dialysis in a pharmaceutical manufacturing setting or in a hospital
- Quality control of preparations for dialysis in a regulatory authority
- Assessment of the relevant parts of applications for marketing authorisation within a medicines agency
- Quality control of preparations for dialysis in an independent testing laboratory
- Analytical procedure development and verification in a regulatory authority

EDSForm Working Party (European drug shortages Formulary)

Terms of reference

- Establishment and maintenance of the CD-P-PH & EPC approved framework for the European Drug Shortages Formulary describing the following items:
  - Criteria and guidelines for the selection, prioritisation and evaluation of appropriate pharmaceutical preparations from national formularies and other appropriate sources, taking into account relevant lists of essential medicines established by European competent authorities, that could be used to mitigate the negative impacts of potential drug shortages
  - Criteria for evaluation of the suitability of production and quality control methods
  - Guidelines for the elaboration of monographs covering working methods, content and template
  - Guidelines for maintenance and vigilance of published monographs including criteria for revision/deletion and procedure for users/stakeholders/interested parties to raise potential issues.
- Selection, prioritisation, elaboration and revision of monographs describing standardised stock preparations of human medicines at risk of shortages according to the criteria and guidelines of the above-mentioned framework.
- In the event of active drug shortage, provide, if and when relevant, recommendations and guidance concerning pharmaceutical preparations that could be used to mitigate the negative impacts of the drug shortage.
- Establishment and maintenance of a respective Technical Guide and General Notices.

*Profile for experts**

- Current expertise in development and production of pharmaceutical extemporaneous and stock preparations
- Current expertise in analytical procedures related to quality control of ingredients (APIs and excipients) and pharmaceutical preparations and in their development
- Access to preparation or laboratory facilities for verification of production methods and analytical procedures proposed for inclusion in monographs
- Several years of experience in one or more of the following fields:
  - Pharmaceutical development and/or manufacturing of extemporaneous and stock pharmaceutical preparations (in a community or hospital pharmacy, research unit, or in pharmaceutical industry)
  - Analytical procedure development and verification of medicinal preparations in a pharmaceutical manufacturing setting (including research and development), in a regulatory authority, in a community or hospital pharmacy or in an independent testing laboratory
  - Market surveillance of quality in a regulatory authority

- Assessment of the relevant parts of applications for marketing authorisation of medicinal products (including safety assessment)
- Elaboration/assessment of monographs for national or regional formularies

*Observer(s) from the CD-P-PH are welcome to participate, especially during the establishment of the framework

EXP Working Party (Excipient performance)

Terms of reference

- Drafting and maintaining the FRC (Functionality Related Characteristics) sections of monographs on excipients to reflect current best practices, in consultation with the appropriate Groups of Experts or Working Parties of the Ph. Eur.
- Review, where necessary, and maintenance of general chapter 5.15 FRCs of excipients to align it with current regulatory guidance (e.g. ICH Q8 guideline)
- Drafting and maintenance of the text on co-processed excipients
- Review pharmacopoeial and other regulatory texts on general information on excipients with a view to proposing necessary additions and updates, where relevant

Profile for experts

- Current expertise in analytical procedures (especially those included in the Ph. Eur. section 2.9. Pharmaceutical technical procedures), related to control of excipients and in development of such analytical procedures
- Several years of experience in one or more of the following fields:
  - Quality control of excipients in a bulk or pharmaceutical manufacturing setting
  - Pharmaceutical and excipient research and development
  - Assessment of the relevant parts of applications for marketing authorisation within a medicines agency
  - Development of analytical procedures for control of excipients, comprising those to determine excipient performance (FRCs) in a research and development environment
  - Pharmaceutical quality control in an independent testing laboratory

EXS Working Party (Excipient Strategy)

Terms of reference

- Identify and discuss best possible approach(es) to address the quality and the standard setting process of excipients for pharmaceutical use in the Ph. Eur. in view of making concrete recommendations to the Ph. Eur. Commission.

  This would include, but is not limited to:
  - the typical structure and content of an individual monograph on such an excipient
  - the evaluation of the need for optional test(s) depending on the possible uses of the excipients (e.g. FRC section)
  - the evaluation of the need for (a) specific technical guide(s)
  - the review of terms of reference of groups of experts and working parties dealing with such excipients (including repartition of tasks between groups and ways of working between groups),
  - The review of existing general monographs (such as Substances for pharmaceutical use (2034)) to appropriately cover such excipients
- Considering the recent example of *nitrites in excipients*, the specific challenges related to setting specifications for excipients in the Ph. Eur., the discussion around impurities (to cite

some examples), propose appropriate control strategies for excipients and consequently, approaches for elaboration and revision of Ph. Eur. Monographs (general or individual ones) and/or general chapters for excipients for pharmaceutical use

Profile for experts

- Ideally a representative (e. g. Chairs) of each group dealing with excipients (esp. groups 9, 13H and CEL, CRB, EXP working party)
- Current expertise in pharmaceutical analytical procedures, related to quality control of excipients for pharmaceutical use and in development of such analytical procedures
- Several years of experience with excipients in one or more of the following fields:
    - Assessment of the relevant parts of applications for marketing authorisation within a medicines agency
    - Market surveillance testing
    - Quality control or development of excipients for pharmaceutical use
    - Development and verification of analytical procedures

The EXS WP may preferably be chaired by a member of the Ph. Eur. Commission.

GLS Working Party (Glass Containers)

Terms of reference

- Drafting and revision of texts in the field of glass containers

Profile for experts

- Current expertise in the production of glass containers, analytical procedures, related to quality control of glass containers and in development of such analytical procedures
- Access to laboratory facilities for verification and validation of analytical procedures proposed for inclusion in general chapters
- Several years of experience in one or more of the following fields:
    - Quality control in a pharmaceutical manufacturing setting for control of glass containers
    - Production and/or quality control of glass containers in an industrial setting
    - Market surveillance of quality in a regulatory authority
    - Pharmaceutical quality control in an independent testing laboratory
    - Development of analytical procedures for control of glass containers in a research and development environment

GTP Working Party (Gene Therapy Products)

Terms of reference

- Drafting and revision of texts in the field of gene therapy medicinal products
- Maintaining regular exchanges to ensure coordination of approaches with the CTP Working Party in relevant areas

Profile for experts

- Current expertise in analytical procedures related to development and quality control of gene therapy products and in development of such analytical procedures
- Several years of experience in one or more of the following fields:
    - Development of gene therapy products

- Quality control of gene therapy products in a pharmaceutical manufacturing setting or in a hospital environment
- Assessment of applications for marketing authorisation of gene therapy products
- Marketing surveillance of quality in a regulatory authority
- Pharmaceutical quality control in an independent testing laboratory
- Development of analytical procedures for control of gene therapy products in a research and development environment

HM Working Party (Heavy metals)

Terms of reference

- Drafting and revision of the general chapter 5.20 Elemental impurities. In this context, identification of technical issues which need to be addressed by ICP working party such as sample preparation and instrumental determination by *atomic emission spectrometry*, *inductively coupled plasma - atomic emission spectrometry* and *inductively coupled plasma - mass spectrometry* and which would require an update of the respective general methods.
- International harmonisation of chapter 2.4.20 (PDG item G-07)

Profile for experts

- Up-to-date substantial expertise in pharmaceutical analytical procedures, related to quality control of active substances and excipients allowing a holistic view on the occurrence of metals from either synthesis or contamination
- Several years of experience in one or more of the following fields:
  - Quality control in a pharmaceutical manufacturing setting
  - Quality control of synthetic and semi-synthetic organic products in a bulk manufacturing setting
  - Assessment of the relevant parts of applications for marketing authorisation within a medicines agency
  - Pharmaceutical quality control of active substances and /or excipients in an independent testing laboratory specialised in testing for metals as residues from synthesis or contaminants

HMM Working Party (Homoeopathic Manufacturing Methods)

Terms of reference

- Drafting and revision of monographs in the field of homoeopathic manufacturing methods

Profile for experts

- Knowledge of currently used homoeopathic manufacturing methods
- Several years of experience in one or more of the following fields:
  - Assessment of application for marketing authorisation of homoeopathic products within a medicines agency or equivalent
- Industry representatives are normally not appointed to the HMM Working Party. They may be invited to contribute to elaboration of monographs during hearings organised on a case-by-case basis by the Secretariat

HOM Working Party (Homoeopathic Raw Materials and Stocks)

Terms of reference

- Drafting and revision of texts in the field of homoeopathic raw materials and stocks

Profile for experts

- Current expertise in pharmaceutical analytical procedures, related to quality control of homoeopathic raw materials and stocks and in development of such analytical procedures
- Access to laboratory facilities for verification and validation of analytical procedures proposed for inclusion in monographs, **Essential**: Active involvement in laboratory verification of analytical procedures and drafting of texts
- Several years of experience in one or more of the following fields:
    - Quality control of homoeopathic raw materials and stocks in a pharmaceutical manufacturing setting
    - Assessment of applications for marketing authorisation of homoeopathic products within an agency
    - Quality control of homoeopathic raw materials and stocks in an independent testing laboratory
    - Development of analytical procedures for control of homoeopathic raw materials and stocks in a research and development environment
    - Analytical procedure development, and verification in a regulatory authority

HTS Working Party (High Throughput Sequencing for the detection of extraneous agents)

Terms of reference

- Elaboration of general chapter *2.6.41* to describe High Throughput Sequencing (HTS) methods for the detection of extraneous agents and provide guidelines for their validation
- To advise the Commission and Groups of Experts on the need to revise other Ph. Eur. texts, further to the elaboration of general chapter *2.6.41* and provide support to Group of Experts requiring the inclusion of HTS methods for extraneous agent detection in their texts

Profile for experts

- Current expertise in HTS **for the detection of extraneous agents** in biologicals, and in the development and validation of analytical procedures based on HTS
- Several years of experience in one or more of the following fields:
    - Use of HTS techniques for quality control of biological products in a pharmaceutical manufacturing setting, a regulatory authority or an independent testing laboratory
    - Development and validation of analytical procedures based on HTS for the detection of extraneous agents, in a research and development environment
    - Assessment of the relevant parts of applications for marketing authorisation within a medicines agency

ICP Working Party (Inductively-Coupled Plasma)

Terms of reference

- Drafting and revision of texts in the field of *atomic absorption spectrometry*, *atomic emission spectrometry*, *inductively coupled plasma - atomic emission spectrometry* and *inductively coupled plasma - mass spectrometry*

Profile for experts

- Current expertise in the development, and application of analytical procedures involving the above mentioned techniques
- Several years of experience in one or more of the following fields:

- Quality control of herbal drugs, herbal drug preparations, synthetic, semi-synthetic, natural origin, biological or biotechnological products in a pharmaceutical setting
- Quality control in a regulatory authority or an independent testing laboratory

INH Working Party (Inhalations)

Terms of reference

- Drafting and revision of monographs and general chapters in the field of preparations for inhalation and nasal sprays or powders.
- International harmonisation of related general chapters

Profile for experts

- Current expertise in pharmaceutical analytical procedures, related to quality control of preparations for inhalation and nasal sprays or powders and in development of such analytical procedures
- Several years of experience in one or more of the following fields related to preparations for inhalation and nasal sprays or powders:
  - Quality control in a pharmaceutical manufacturing setting
  - Market surveillance of quality in a regulatory authority
  - Assessment of applications for marketing authorisation within a medicines agency
  - Development of analytical procedures for control of such preparations in a research and development environment
  - Pharmaceutical quality control in an independent testing laboratory
  - Analytical procedure development and verification in a regulatory authority

MAB Working Party (Monoclonal Antibodies)

Terms of reference:

- To undertake a pilot phase to elaborate general methods for analysis of monoclonal antibodies and individual monographs using the multisource approach (according to document PA/PH/Exp. MAB/T (14) 1)
- Drafting and revision of texts in the field of monoclonal antibodies

Profile for experts

- Current expertise in pharmaceutical analytical procedures, related to quality control of monoclonal antibodies and in development of such analytical procedures
- Access to laboratory facilities for verification and validation of analytical procedures proposed for inclusion in monographs or access to licensing files. **Essential**: Active involvement in laboratory verification of analytical procedures and drafting of texts
- Several years of experience in one or more of the following fields:
  - Quality control of monoclonal antibodies in a pharmaceutical manufacturing setting
  - Market surveillance of quality in a regulatory authority
  - Assessment of applications for marketing authorisation of monoclonal antibodies within an agency
  - Development of analytical procedures for control of monoclonal antibodies in a research and development environment
  - Pharmaceutical quality control in an independent testing laboratory

MG Working Party (General methods)

Terms of reference

- Drafting and revision of general chapters, particularly in the field of chemical and physico-chemical analysis.
- If needed, requests the nomination of ad hoc specialists to create sub-groups for specific general chapters on the work programme, and management of the activities for the elaboration or revision of these general chapters within the sub-groups.
- Co-operation with other groups of experts and working parties which are in charge of elaboration and revision of general chapters where relevant.
- Maintenance of template for general methods

Profile for experts

- Members of a regulatory authority, universities or the pharmaceutical/chemical industries
- Current expertise and extensive knowledge in pharmacopoeial procedures and/or instruments used in the quality control of active substances, excipients and/or medicinal products and in development of analytical procedures
- Several years of experience in one or more of the following fields:
    - Analytical procedure development and verification in e.g. analytical or pharmaceutical development, a regulatory authority, or testing laboratory
    - Quality control of active substances, excipients and/or medicinal products
    - Market surveillance of quality of medicinal products in a regulatory authority
    - Assessment of the relevant parts of applications for marketing authorisation within a medicines agency

mRNAVAC Working Party (mRNA Vaccines for human use)

Terms of reference

- Drafting and revision of texts in the field of mRNA vaccines for human use

Profile for experts

- Current expertise in analytical procedures related to the quality control of mRNA vaccines for human use, their components and their formulation
- Significant experience in one or more of the following fields:
    - Quality control of mRNA vaccines for human use and their components in a pharmaceutical manufacturing setting
    - Quality control/batch release/market surveillance of mRNA vaccines for human use and their components in an independent testing laboratory (e.g. OMCL)
    - Pharmaceutical development related to the formulation of mRNA vaccines for human use
    - Analytical development related to mRNA vaccines for human use and their components
    - Assessment of the relevant parts of applications for marketing authorisation within a medicines agency

MYC Working Party (Mycoplasma)

Terms of reference

- Revision of general chapter *2.6.7 Mycoplasmas* in order to update it with the current practices in the field of mycoplasma testing

Profile for experts

- Current expertise in mycoplasma testing of medicinal products and in development of analytical procedures
- Access to laboratory facilities for verification and validation of analytical procedures proposed for inclusion in monographs,
- Several years of experience in one or more of the following fields:
    - Mycoplasma testing in a pharmaceutical manufacturing setting
    - Mycoplasma testing in an official control laboratory for medicines
    - Mycoplasma testing in an independent testing laboratory
    - Development of analytical procedures for mycoplasmas in a research and development environment

NANO Working Party (Nanomedicines)

Terms of reference

- Drafting and revision of texts in the field of nanomedicines (e.g. nanoparticle dispersions, like for example iron sucrose concentrated solution, liposomal formulations, and related analytical procedures)
- Provision of expertise in the field of nanomedicines to other groups where relevant

Profile for experts

- Current expertise in the development and/or quality control of nanomedicines and in development of relevant analytical procedures
- Access to laboratory facilities for verification and validation of analytical procedures proposed for inclusion in monographs, **Essential**: Active involvement in laboratory verification of analytical procedures and drafting of texts
- Several years of relevant experience in one or more of the following fields:
    - Quality control in a pharmaceutical manufacturing setting or in an independent testing laboratory (e.g. Market surveillance of quality in a regulatory authority) related to respective formulations
    - Pharmaceutical development related to respective formulations
    - Development of analytical procedures related to respective formulations
    - Assessment of the relevant parts of applications for marketing authorisation within a medicines agency

P4BIO Working Party (P4 Bio)

Terms of reference

- Drafting and revision of monographs in the field of single-source biologicals

Profile for experts

- Group P4Bio is restricted to regulators from Ph. Eur. Member states however industry representatives may be invited to contribute by submission of data and interaction with the group via the Secretariat

- Current expertise in pharmaceutical analytical procedures, related to quality control of biologicals and in development of such analytical procedures
- Access to laboratory facilities for verification and validation of analytical procedures proposed for inclusion in monographs or access to licensing files (essentially originating from CAP), **Essential**: Active involvement in laboratory verification of analytical procedures and drafting of texts and
- Several years of experience in one or more of the following fields:
    - Quality control in a regulatory authority
    - Assessment of the relevant parts (biologicals) of applications for marketing authorisation
    - Market surveillance of quality in a regulatory authority

PaedF Working Party (European Paediatric Formulary)

Terms of reference

- Elaboration, and revision of monographs on paediatric preparations according to criteria and guidelines approved by the CD-P-PH
- Establishment and maintenance of a Technical Guide for the elaboration and maintenance of monographs on paediatric preparations

Profile for experts

- Current expertise in development and production of paediatric preparations (including toxicologists)
- Current expertise in analytical procedures related to quality control of ingredients (APIs and excipients) and preparations and in the development of such preparations and analytical procedures; Access to laboratory facilities for verification of production methods and analytical procedures proposed for inclusion in monographs
- Current expertise in clinical/pharmacological treatment of several paediatric age groups
- Several years of experience in one or more of the following fields:
    - Pharmaceutical development and/or manufacturing of paediatric preparations (in a community or hospital pharmacy, research unit, or in pharmaceutical industry)
    - Analytical procedure development and verification of medicinal preparations in a pharmaceutical manufacturing setting (including research and development), in a regulatory authority, in a community or hospital pharmacy or in an independent testing laboratory
    - Market surveillance of quality in a regulatory authority
    - Assessment of the relevant parts of applications for marketing authorisation of paediatric medicinal products (including safety assessment)
    - Elaboration/assessment of monographs for national (paediatric) formularies
    - Clinical/pharmacological treatment of children belonging to several age groups

PAT Working Party (Process Analytical Technology)

Terms of reference

- Review and revision of existing general monographs and chapters in view of needs arising from Process Analytical Technology (PAT), Continuous Manufacturing (CM), Real Time release testing (RTRT) or Quality by Design (QbD) concepts
- Identify and discuss the implication of the above mentioned concepts on the texts of European Pharmacopoeia and make proposals to the Commission where needed

- Support and advise other group of experts and working parties where elements of the above mentioned concepts are concerned.

Profile for experts

- Expertise in chemical or pharmaceutical development and analytical procedures applied during manufacture and to active substances or finished pharmaceutical preparations
- Several years of experience in one or more of the following fields
    - Development of pharmaceutical preparations using PAT, CM, RTRT or QbD concepts in an industrial setting
    - Assessment of the relevant parts of applications for marketing authorisation containing PAT, CM, RTRT or QbD concepts within a medicines agency
    - Development of control strategies including PAT, CM, RTRT or QbD concepts approaches for testing of active substances or pharmaceutical preparations
    - Development of pharmaceutical preparations using modelling and chemometrics associated with the analytical aspects for PAT

POW Working Party (Powder Characterisation)

Terms of reference

- Drafting and revision of general chapters in the field of powder characterisation techniques
- International harmonisation of general chapters

Profile for experts

- Current expertise in analytical procedures for powder characterisation, related to quality control of active substances and excipients and in development of such analytical procedures
- Several years of experience in one or more of the following fields:
    - Quality control of active substances and excipients in a pharmaceutical manufacturing setting
    - Assessment of the relevant parts of applications for marketing authorisation
    - Market surveillance of quality in a regulatory authority
    - Development of analytical procedures for characterisation of powders in a research and development environment
    - Pharmaceutical quality control in an independent testing laboratory

PRP Working Party (Precursors for Radiopharmaceutical Preparations)

Terms of reference

- Drafting and revision of texts in the field of non-radioactive precursors for radiopharmaceutical preparations

Profile for experts

- Expertise in chemical, pharmaceutical and radiopharmaceutical analytical procedures, related to quality control of radiopharmaceutical preparations and their precursors
- Access to laboratory facilities for verification and validation of analytical procedures proposed for inclusion in monographs. **Essential**: Active involvement in laboratory verification of analytical procedures and drafting of texts
- Several years of experience in one or more of the following fields:
    - Quality control of radiopharmaceutical preparations and their precursors
    - Quality control of synthetic organic and/or inorganic products in a chemical or pharmaceutical setting

- Quality control in an independent testing laboratory
- Development of analytical procedures for the control of radiopharmaceutical preparations and their precursors

PST Working Party (Pesticide Residues)

Terms of reference

- Drafting and revision of texts in the field of pesticide residues

Profile for experts

- Current expertise in pesticide analysis, related to quality control of active substances and excipients and in development of such analytical procedures
- Access to laboratory facilities for verification and validation of analytical procedures proposed for inclusion in monographs
- Several years of experience in one or more of the following fields:
  - Quality control for pesticide residues in herbals in a pharmaceutical or bulk manufacturing setting
  - Market surveillance of quality in a regulatory authority
  - Pharmaceutical quality control in an independent testing laboratory
  - Development of analytical procedures for pesticide residues in a research and development environment

ROP Working Party (Rules of Procedure)

Terms of reference

Addressing the following topic:

- Handling of official Ph. Eur. documents, information and data
- Implication of the EU General Data Protection Regulation (GDPR) on the Ph. Eur. code of practice and provision of contact details (incl. handbook)
- Pilot Projects and pilot phase: clarification of definition, process, criteria
- Review of the re-nomination process of members of Groups of Experts and Working Parties
- Post COVID-19 – Digital Transformation: opportunities for adjustment of working methods (e.g. establishment of electronic workflows, organisation of visio-conferences and webinars)

As the impact on the Rules of Procedure, on the Guide for work of the European Pharmacopoeia and on the Code of practice is not known yet, the work is carried out in two steps:

- The first step includes for each of the points highlighted above,
  a. To clarify the remit or scope,
  b. To agree on the expected / wished outcome
  c. To assess the impact on the documents mentioned above (i.e. which section of which document)
  d. To report back to the Commission for the latter to decide to move to step 2 or not
- If the Commission agrees to move to step 2, the ROP WP would revise the impacted documents i.e. the Rules of Procedure and/or the Guide for work of the European Pharmacopoeia and/or the Code of Practice according to the decision taken by the Commission after step 1.

In addition to the above:

- Make concrete recommendations on the (de)classification of documents distributed by the European Pharmacopoeia Department in the framework of the Ph. Eur. (e.g. in the form of a guide) for approval by the Commission

- Support the implementation of the revised Rules of Procedure, Guide for work and Code of Practice (eg in form of powerpoint presentations, webinars or any other mean deemed appropriate by the ROP WP members to ensure consistent and appropriate dissemination of the information provided and changes made as well as their application)

Profile for experts

- Members of national pharmacopoeia authorities of a Ph. Eur. Member state or delegations to the Commission.

The ROP WP is chaired by the Chair of the Ph. Eur. Commission.

SDA Working Party (Spectroscopy and Data Analysis)

Terms of reference

- Drafting and revision of general chapters in the fields of:
  - Measurement techniques relying on spectroscopy, with the exception of specific spectroscopic techniques where the drafting and revision of general chapters is allocated to other, more specialised groups of experts and working parties.
  - Chemical imaging techniques, e.g. spectral and multispectral imaging, electron microscopy, field effect and atomic force microscopies, optical and X-ray tomography, etc.
  - Chemometrics and data sciences techniques relying on multivariate data analysis, numerical methods, algorithmics, data modelling, data mining, artificial intelligence, etc., and image analysis techniques.
- to support and advise other group of experts and working parties where elements of the above mentioned measurement and data analysis techniques are concerned and where relevant.

Profile for experts

- Current expertise in spectroscopy related to quality control of active substances, excipients or medicinal products, in development of analytical procedures.
- Ideally, access to laboratory facilities for verification and validation of analytical procedures proposed for inclusion in general chapters and monographs
- Several years of experience in one or more of the following fields:
  - Use of spectroscopic techniques for pharmaceutical quality control in a pharmaceutical manufacturing setting, a regulatory authority or an independent testing laboratory.
  - Development of pharmaceutical in-, on-, or at-line analytical procedures using spectroscopic or imaging techniques or chemometrics and data analysis, in a research and development environment.
  - Assessment of applications for marketing authorisation.
  - Use of spectroscopic techniques for the market surveillance of the quality of pharmaceutical substances or medicinal products.

SIT Working Party (Second identification test)

Terms of reference

- To support and advise the Commission, Groups of Experts or Working Parties on revision/suppression of existing identification series, notably arising from the REACH regulation, where relevant.
  Propose to the Commission further items for the work programme (such as monographs with missing second identification or the replacement of identification tests not in line with the instrumentation available in pharmacies)

Profile for experts

- Pharmacists regularly involved in preparation of extemporaneous or stock preparation of medicinal products in community pharmacies or hospitals as well as in the analysis of the pharmaceutical substances used
- Pharmacists or chemists with special interest/expertise in analytical techniques commonly available in pharmacies
- Members of a regulatory authority
- Access to laboratory facilities for verification of analytical procedures proposed for inclusion in monographs

ST Working Party (Standard Terms)

Terms of reference

- Development of standard terms and definitions for the Standard Terms database for dosage forms, units of presentation, routes of administration, packaging and related terms at the request of Competent authorities of Member States and certain non-member states (e.g. competent authority members of ICH), the European Commission or the EMA.

Profile for experts

- Current expertise in pharmaceutical dosage forms
- Several years of experience in one or more of the following fields:
    - Assessment of the pharmaceutical development part of applications for authorisation of medicinal products
    - Development of general monographs for dosage forms (group of experts or national pharmacopoeia secretariat)
    - Experience in formulation of medicinal products
- Members of the working party may be from a regulatory authority or universities

SUT Working Party (Sutures)

Terms of reference

- Drafting and revision of texts in the field of sutures

Profile for experts

- Expertise in pharmaceutical analytical procedures, related to quality control of sutures and in development of such analytical procedures
- Several years of experience in one or more of the following fields:
    - Quality control of sutures
    - Development of analytical procedures for control of sutures

TCM Working Party (Traditional Chinese Medicines)

Terms of reference

- Drafting and revision of texts in the field of herbal drugs and herbal drug preparations preferably based on the principle of adapting/improving existing monographs or analytical procedures to control herbal drugs used in Traditional Chinese Medicines (TCM)
- Drafting general chapters related to the specific needs of TCM herbal drugs

Profile for experts

- Current expertise in pharmaceutical analytical procedures, related to quality control of herbal drugs and herbal drug preparations and in development of such analytical procedures
- Access to laboratory facilities for verification and validation of analytical procedures proposed for inclusion in monographs
- Several years of experience in one or more of the following fields:
    - Quality control of herbal drugs/herbal drug preparations in a manufacturing setting
    - Pharmaceutical quality control of herbal drugs and herbal drug preparations in an independent testing laboratory
    - Development and validation of analytical procedures for control of herbal drugs
    - Involvement in market surveillance or regulatory oversight of imported TCM herbal drugs
- **Essential**: Active involvement in laboratory verification of analytical procedures for TCM herbal drugs and in drafting of texts.
- Development and validation of analytical procedures for identification and/or quantification of herbal drug constituents based on chromatographic separation techniques (HPLC, GC, HPTLC)
- Knowledge in cultivation, harvesting, processing and use of TCM herbal drugs

VIT Working Party (Vitamins)

Terms of reference

- Drafting and revision of monographs in the field of vitamins and vitamin derivatives

Profile for experts

- Current expertise in pharmaceutical analytical procedures, related to quality control of vitamins and excipients and in development of such analytical procedures. *The need of a specialist for vitamin D type substances is highlighted*
- Access to laboratory facilities for verification and validation of analytical procedures proposed for inclusion in monographs, **Essential**: Active involvement in laboratory verification of analytical procedures and drafting of texts.
- Several years of experience in one or more of the following fields:
    - Quality control of vitamins in a pharmaceutical or bulk manufacturing setting
    - Market surveillance of quality in an official control laboratory for medicines
    - Pharmaceutical quality control in an independent testing laboratory
    - Development of analytical procedures for control of vitamins in a research and development environment
    - Analytical procedure development and verification in a national pharmacopoeia laboratory

WAT Working Party (Water)

Terms of reference

- Drafting and revision of texts in the field of water
- International harmonisation of relevant texts

Profile for experts

- Current expertise in analytical procedures applicable to water analysis and in development of such analytical procedures
- Several years of experience in one or more of the following fields:
    - Quality control of water in a pharmaceutical manufacturing setting
    - Inspection of manufacturing sites
    - Pharmaceutical quality control in an independent testing laboratory
    - Development of analytical procedures for control of pharmaceutical waters in a research and development environment

TERMS OF REFERENCE AND PROFILE FOR MEMBERS OF "DORMANT" WORKING PARTIES:

Once a working party has finalised its work programme i.e. the text(s) elaborated or revised by the working party has(have) been adopted by the Commission, the mandate of the working party can be extended as the support and advice of Pharmacopoeia members may still be needed e.g. by other Ph. Eur. groups or by the Secretariat to answer to questions users may rise when implementing the texts for example. The task of this working party will mainly consist in answering to enquiries, questions sent via the Secretariat i.e. by correspondence. The terms of reference of these working parties are described accordingly.

CND Working Party (Conductivity)

Terms of reference

- To provide support and advice in case of questions raised by e.g. users related to the PDG harmonised general chapter *2.2.38 Conductivity*

Profile for experts

- Current expertise in conductivity measurement
- Several years of experience in one or more of the following fields:
    - Quality control using conductivity measurement in a pharmaceutical manufacturing setting
    - Market surveillance of quality using conductivity measurement in a regulatory authority
    - Conductivity measurement for pharmaceutical analysis in an independent testing laboratory
    - Conductivity measurement in a regulatory authority
    - Development of analytical procedures for conductivity measurement in a research and development environment

CRP Working party (Production and compounding of radiopharmaceutical preparations)

Terms of reference

- To provide support and advice in case of questions raised in the field of production and compounding of radiopharmaceutical preparations (especially chapter 5.19 *Extemporaneous preparation of radiopharmaceuticals*).

Profile for experts

- Knowledge of the current legal framework for the preparation or compounding of radiopharmaceuticals and quality control of such preparations, or experience in the licensing of such preparations
- Several years of experience in the field of manufacture and quality control of radiopharmaceutical preparations and their starting materials in a pharmaceutical industry setting; in a PET centre or in a hospital

EXT Working Party (Extracts)

Terms of reference

- To provide support and advice in case of questions raised by e.g. users in the field of Herbal drug extracts

Profile for experts

- Several years of experience in one or more of the following fields:
    - Assessment of the relevant parts of applications for marketing authorisation of herbal medicinal products within a medicines agency
    - Production or quality control of extracts for further use in herbal medicinal products
    - Production or quality control of herbal medicinal products containing extracts

GEL Working Party (Gelatin)

Terms of reference

- To provide support and advice in case of questions raised by e.g. users in the field of gelatin

Profile for experts:

- Current expertise in pharmaceutical analytical procedures, related to quality control of gelatin and in development of such analytical procedures
- Access to laboratory facilities for verification and validation of analytical procedures proposed for inclusion in monographs, **Essential**: Active involvement in laboratory verification of analytical procedures and drafting of texts.
- Several years of experience in one or more of the following fields:
    - Quality control in a pharmaceutical or bulk manufacturing setting (gelatin or use of gelatin)
    - Market surveillance of quality in a regulatory authority
    - Pharmaceutical quality control in an independent testing laboratory
    - Analytical procedure development and verification in a regulatory authority
    - Development of pharmaceutical analytical procedures using near infrared spectroscopy for gelatin identification

HCP Working Party (Host-Cell Proteins)

Terms of reference

- To provide support and advice in case of questions raised by e.g. users related to the Chapter on Host Cell Protein Assays (2.6.34) and propose potential revision of the chapter after evaluation of its implementation

Profile for experts

- Current expertise in analytical procedures and testing strategies related to quality control of residual levels of host-cell proteins (including proteomic approaches)
- Several years of experience in one or more of the following fields:
    - Quality control of recombinant proteins
    - Development and validation of manufacturing and purification processes for recombinant proteins
    - Development and validation of in-house analytical procedures for host-cell protein detection and quantification
    - Validation of commercial generic kits for a given protein and process
    - Assessment of the relevant parts of applications for marketing authorisations within a medicines agency

HFA Working Party (Propellant Gases)

Terms of reference

- To provide support and advice in case of questions raised by e.g. users in the field of propellant gases

Profile for experts:

- Current expertise in pharmaceutical analytical procedures , related to quality control of propellant gases and in development of such analytical procedures
- Several years of experience in one or more of the following fields:
  - Quality control of propellant gases in a pharmaceutical or bulk manufacturing setting
  - Assessment of the relevant parts of applications for marketing authorisation of medicinal products containing propellant gases
  - Market surveillance of quality in a regulatory authority
  - Pharmaceutical quality control in an independent testing laboratory
  - Development of analytical procedures for control of propellant gases in a research and development environment

LBP Working Party (Live Biotherapeutic Products)

Terms of reference

- To provide support and advice in case of questions raised by e.g. users related to Live Biotherapeutic Products

Profile for experts

- Current expertise in the development, production and/or quality control of Live Biotherapeutic Products
- Several years of experience in one or more of the following fields:
  - development of Live Biotherapeutic Products
  - production of Live Biotherapeutic Products
  - assessment of applications for licensing of Live Biotherapeutic Products
  - micro-organism strain selection and batch production
  - microbiological techniques, molecular techniques applied to microbiology

LEC Working Party (Lecithins)

Terms of reference

- To provide support and advice in case of questions raised by e.g. users in the field of lecithins

Profile for experts

- Current expertise in pharmaceutical analytical procedures, related to quality control of lecithins and in development of such analytical procedures
- Access to laboratory facilities for verification and validation of analytical procedures proposed for inclusion in monographs, **Essential**: Active involvement in laboratory verification of analytical procedures and drafting of texts
- Several years of experience in one or more of the following fields:
  - Quality control of lecithins in a pharmaceutical or bulk manufacturing setting
  - Market surveillance of quality in a regulatory authority
  - Pharmaceutical quality control in an independent testing laboratory

- Development of analytical procedures for control of lecithins in a research and development environment
- Analytical procedure development and verification in a regulatory authority

MQH Working Party (Microbiological Quality of Herbal Drugs)

Terms of reference

- To provide support and advice in case of questions raised by e.g. users and related to recommendations on microbiological quality of herbal drugs and herbal drug preparations
- Advising the Commission and its groups on acceptance criteria for microbiological criteria to be included in monographs

Profile for experts:

- Current expertise in pharmaceutical analytical procedures, related to microbiological quality control of active substances and excipients and in development of such analytical procedures
- Several years of experience in one or more of the following fields:
  - Microbiological quality control in a pharmaceutical or bulk manufacturing setting
  - Market surveillance of quality in a regulatory authority
  - Assessment of applications for marketing authorisation of herbal drugs and herbal drug preparations within an agency
  - Development of microbiological analytical procedures for control of herbal drugs and herbal drug preparations in a research and development environment
  - Pharmaceutical quality control in an independent testing laboratory
  - Analytical procedure development and verification in a regulatory authority

MSL Working Party (Mesilates)

Terms of reference

- To provide support and advice in case of questions raised related to general methods drafted by the working party i.e. *2.5.37. Methyl, ethyl and isopropyl methanesulfonate in methanesulfonic acid, 2.5.38. Methyl, ethyl and isopropyl methanesulfonate in active substances, 2.5.39. Methanesulfonyl chloride in methanesulfonic acid, 2.5.40. Methyl, ethyl and isopropyl toluenesulfonate in active substances, 2.5.41 Methyl, ethyl and isopropyl benzenesulfonate in active substances*

Profile for experts

- Current expertise in pharmaceutical analytical procedures, related to quality control of starting materials
- Access to laboratory facilities (including “hyphenated” techniques (LC-MS, GC-MS, etc.) for verification and validation of analytical procedures proposed for inclusion in monographs
- Several years of experience in one or more of the following fields:
  - Quality control in a pharmaceutical manufacturing setting
  - Quality control of starting materials for synthetic and semi-synthetic organic products in a bulk manufacturing setting
  - Quality control using “hyphenated” techniques (LC-MS, GC-MS, etc.)
  - Market surveillance of quality in a regulatory authority
  - Quality control of starting materials in an independent testing laboratory
  - Development of analytical procedures for control of starting materials in a research and development environment

- Analytical procedure development and verification in a regulatory authority

NMR Working Party (Nuclear Magnetic Resonance Spectrometry)

Terms of reference

- To provide support and advice in case of questions raised by e.g. users in the field of nuclear magnetic resonance spectrometry

Profile for experts:

- Current expertise in NMR, related to quality control of active substances and excipients and in development of analytical procedures using NMR
- Several years of experience in one or more of the following fields:
  - Quality control using NMR in a pharmaceutical or bulk manufacturing setting
  - Market surveillance of quality in a regulatory authority
  - Pharmaceutical quality control in an independent testing laboratory
  - Development of pharmaceutical analytical procedures using NMR in a research and development environment

PA Working Party (Pyrrolizidine alkaloids)

Terms of reference

- To provide support and advice in case of questions raised by e.g. users in the field of Pyrrolizidine alkaloids.

Profile for experts

- Current expertise in PA analysis, related to quality control of herbal drugs and in development of analytical procedures.
- Access to laboratory facilities for quality control. Essential: active involvement in laboratory verification of analytical procedures and drafting of texts
- Several years of experience in one or more of the following fields:
  - Quality control of herbals in a pharmaceutical or bulk manufacturing setting, in a regulatory authority or in any other specialised testing laboratory;
  - Development and/or lab verification of analytical procedures for control of pyrrolizidine alkaloids in a research and development environment or in a regulatory authority.

PHP Working Party (Pharmaceutical Preparations (general monograph))

Terms of reference

- To support and advise Commission, Groups of Experts or Working Parties on revisions of the general monograph Pharmaceutical Preparations, as needed. Such a need may arise e.g. from changed requirements or from the need to replace repetitive references in monographs by a centrally listed requirement in the general monograph Pharmaceutical Preparations.

Profile for experts

- Extensive knowledge of pharmaceutical development and quality control of medicinal products (licensed or unlicensed)
- Extensive knowledge of regulatory requirements and guidelines for medicinal products
- Several years of experience in one or more of the following fields:

- Pharmaceutical development and quality control of medicinal products (licensed or unlicensed)
- Assessment of the relevant parts of marketing authorisation applications in a medicines agency
- Development of analytical procedures for testing of pharmaceutical preparations in a research and development environment, in a hospital or in a small-scale production setting
- Market surveillance of pharmaceutical preparations in a regulatory authority
- Inspection of retail or hospital pharmacies or of pharmaceutical companies

RCG Working Party (Raw Materials for the production of Cellular and gene transfer products)

Terms of reference

- To provide support and advice in case of questions raised by e.g. users related to the general chapter on *Raw materials of biological origin for the production of cell-based and gene therapy medicinal products (5.2.12)* and propose potential revision of the chapter after evaluation of its implementation

Profile for experts

- Current expertise in the development and/or quality control of cellular and gene transfer products and in development of analytical procedures for the control of these products
- Several years of experience in one or more of the following fields:
  - Development of cell and/or gene transfer products or raw materials used for their production
  - Development of cell culture methods/media
  - Assessment of applications for clinical trials and/or for marketing authorisations of cell and/or gene transfer products

SRP Working Party (Special Revision Programme)

Terms of reference

- To provide support and advice in case of questions raised by e.g. users related to the revision of the related substances tests and limits in monographs in the field of active substances

Profile for experts

- Current expertise in pharmaceutical analytical procedures, related to quality control of active substances and excipients and in development of such analytical procedures
- Access to relevant parts (chemistry of the active substance) of marketing authorisation dossiers in order to judge the revision proposals
- Several years of experience in one or more of the following fields:
  - Scientific coordination in a regulatory authority such as a National Pharmacopoeia Authority
  - Assessment of the relevant parts (chemistry of the active substance) of applications for marketing authorisation
  - Market surveillance of quality in a regulatory authority
  - Analytical procedure development and verification in a regulatory authority
- Industry representatives are not appointed to the SRP Working Party; they contribute by submission of data and interaction with the group via the Secretariat.

STA Working Party (Statistics)

Terms of reference

- To provide support and advice in case of questions raised by e.g. users in the field of statistical analysis

Profile for experts

- Current expertise in statistical analysis, related to quality control of active substances, excipients and medicinal products
- Several years of experience in one or more of the following fields:
    - Statistical analysis of results of analytical procedures used for quality control in a pharmaceutical manufacturing setting
    - Development of statistical methods applied in pharmaceutical analysis

WXT Working Party (Water for Extracts)

Terms of reference

- To provide support and advice in case of questions raised by e.g. users in the field of water for the preparation of extracts

Profile for experts:

- Current expertise in analytical procedures for water analysis, related to the water used for preparation of extracts
- Several years of experience in one or more of the following fields:
    - Quality control of water used for the preparation of extracts in a pharmaceutical manufacturing setting
    - Assessment of the relevant parts of applications for marketing authorisation of extracts
    - Pharmaceutical quality control in an independent testing laboratory
    - Development of analytical procedures for control of water in a research and development environment