European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

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(EUROPEAN PHARMACOPOEIA COMMISSION)

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

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NOTE: The mandate of the ST WP has been revised as discussed at the 155th session of the Ph. Eur. Commission.

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 expert and working party will advise the Commission 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, P4. The Chair of the Ph. Eur. Commission is chairing the PCM working party. The chairs of the other groups of experts and working parties may be invited on an ad hoc basis, depending on the agenda.

INDEX:

Group of Experts No. 1 (Microbiology)

Terms of reference

- Drafting and revision of general chapters allocated to the group by the Commission 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 where decided by the Commission
- Drafting and revision of general chapters allocated to the group by the Commission in the field of alternative microbiological methods (the so called "rapid" methods)

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 monographs and general chapters allocated to the group by the Commission in the field of biological products, biotechnological products, synthetic peptides including glycan mapping
- International harmonisation of general chapters in the field of biological products where decided by the Commission

Profile for experts

- Current expertise in quality control of biological products, biotechnological products, peptides
- Access to laboratory facilities for verification of methods proposed for inclusion in monographs, **Essential**: Active involvement in drafting of texts and laboratory verification of test methods
- Several years of experience in one or more of the following fields:
    - Quality control of biological products, biotechnological products, peptides in a pharmaceutical manufacturing setting
    - Quality control in a regulatory authority
    - Quality control of biological or biotechnological products in an independent testing laboratory

- Development of methods for control of biological products, biotechnological products, peptides in a research and development environment
- Method 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

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

- Current expertise in pharmaceutical analytical methods, related to quality control of glycoproteins and in development of control methods
- Several years of experience in one or more of the following fields:
  - Quality control of glycoproteins in a pharmaceutical manufacturing setting
  - Market surveillance of quality of glycoproteins in a regulatory authority
  - Pharmaceutical quality control of glycoproteins in an independent testing laboratory
  - Assessment of the relevant parts of application for marketing authorisation of biological and biotechnological products within a medicines agency
  - Method development and verification in a regulatory authority
  - Development of control methods for glycoproteins in a research and development environment

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

Terms of reference

- Drafting and revision of general chapters and monographs allocated to the group by the Commission in the field of blood products

Profile for experts

- Current expertise in the field of blood products, notably related to quality control of and development of control methods
- Access to laboratory facilities for verification of methods proposed for inclusion in monographs, **Essential**: Active involvement in drafting of texts and laboratory verification of test methods
- 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
  - Development of methods for control Human Plasma and Plasma Products in a research and development environment

Group of Experts No. 7 (Antibiotics)

Terms of reference

- Drafting and revision of monographs and general chapters allocated to the group by the Commission in the field of antibiotics (active substances and/or finished products if / when allocated to the group by the Commission)

Profile for experts

- Current expertise in the fields covered by the terms of reference
- Access to laboratory facilities for verification of methods proposed for inclusion in monographs, **Essential**: Active involvement in drafting of texts and laboratory verification of test methods
- Several years of experience in one or more of the following fields:
  - Quality control of antibiotics (active substances and/or finished products) in a pharmaceutical manufacturing setting

- Quality control of antibiotics (active substances and/or finished products) in a bulk manufacturing setting
- Quality control of antibiotics (active substances and/or finished products) in a regulatory authority
- Assessment of the relevant parts of applications for marketing authorisation within a medicines agency
- Quality control of antibiotics (active substances and/or finished products) in an independent testing laboratory
- Development of methods for control of antibiotics in a research and development environment
- Method development and verification in a regulatory authority

Group of experts No. 9 (Inorganic Chemistry)

Terms of reference

- Drafting and revision of monographs allocated to the group by the Commission in the field of inorganic products
- International harmonisation of monographs where decided by the Commission

Profile for experts

- Current expertise in pharmaceutical analytical methods, related to quality control of inorganic active substances and excipients and in development of control methods
- Access to laboratory facilities for verification of methods proposed for inclusion in monographs, for example ICP and/or AAS. **Essential**: Active involvement in drafting of texts and laboratory verification of test methods
- Several years of experience in one or more of the following fields:
  - Quality control inorganic active substances and excipients 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 methods for control of inorganic products in a research and development environment
  - Method development and verification in a national pharmacopoeia laboratory

Group of Experts No. 9G (Medicinal Gases)

Terms of reference

- Drafting and revision of monographs and general chapters allocated to the group by the Commission in the field of medicinal gases

Profile for experts

- Current expertise in the fields covered by the terms of reference
- Access to laboratory facilities for verification of methods proposed for inclusion in monographs, **Essential**: Active involvement in drafting of texts and laboratory verification of test methods
- 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 methods 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 products)

Terms of reference

- Drafting and revision of monographs allocated to the group by the Commission in the field of synthetic and semi-synthetic organic active substances and excipients
- Drafting and revision of finished product monographs with chemically defined active substance if / when allocated to the group by the Commission

Profile for experts

- Current expertise in pharmaceutical analytical methods, related to quality control of active substances, excipients and finished products with chemically defined active substance and in development of control methods
- Access to laboratory facilities for verification of methods proposed for inclusion in monographs, **Essential**: Active involvement in drafting of texts and laboratory verification of test methods
- 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 active substances, excipients and /or finished products with chemically defined active substances in an independent testing laboratory
  - Development of methods for control of active substances, excipients and /or finished products with chemically defined active substances in a research and development environment
  - Group 10D: development of control methods for amino-acids
  - Method development and verification in a regulatory authority

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

Terms of reference

- Drafting and revision of monographs allocated to the group by the Commission in the field of natural, semi-synthetic and synthetic organic active substances, excipients and finished products if / when allocated to the group by the Commission)

Profile for experts

- Current expertise in pharmaceutical analytical methods, related to quality control of active substances, excipients and finished products and in development of control methods
- Access to laboratory facilities for verification of methods proposed for inclusion in monographs, **Essential**: Active involvement in drafting of texts and laboratory verification of test methods
- 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 products (active substances, excipients and/or finished products) in a bulk manufacturing setting
  - Market surveillance of quality in a regulatory authority
  - Pharmaceutical quality control in an independent testing laboratory
  - Development of methods for control of active substances and /or excipients and/or finished products in a research and development environment
  - Method development and verification in a regulatory authority

Group of Experts No. 12 (Dosage forms and dosage form methods)

Terms of reference

- Drafting and revision of dosage form monographs
- Maintenance of dosage form related International Harmonisation topics such as:
  - uniformity of dosage units

- dissolution
- disintegration

- particulate contamination: sub-visible particles

Profile for experts

- Current expertise in pharmaceutical development and control methods applied during manufacture and to finished 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 methods for testing of pharmaceutical preparations in a research and development environment
  - Method development and verification in a regulatory authority

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

Terms of reference

- Drafting and revision of monographs allocated to the group by the Commission in the field of herbal drugs and herbal drug preparations

Profile for experts

- Current expertise in pharmaceutical analytical methods, related to quality control of herbal drugs and herbal drug preparations and in development of control methods
- Access to laboratory facilities for verification of methods proposed for inclusion in monographs, **Essential**: Active involvement in drafting of texts and laboratory verification of test methods
- 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 methods for control of herbal drugs in a research and development environment
  - Method development and verification in a regulatory authority

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

Terms of reference

- A panel of Specialists is appointed for the drafting and revision of monographs allocated to the group by the Commission in the field of:
  - surfactants
  - fatty oils, fats and waxes
  - fatty acids, fatty alcohols and their esters/ethers
  - macrogols, macrogol derivatives and other polymers (i.e. carbomers)
  - Paraffins
- International Harmonisation of the relevant monographs

Profile for experts

- Current expertise in pharmaceutical analytical methods, related to quality control in the relevant specialities defined in the terms of reference

- Access to laboratory facilities for verification of methods proposed for inclusion in monographs, **Essential**: Active involvement in drafting of texts and laboratory verification of test methods
- 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 methods for control of fats etc. in a research and development environment
    - Method development and verification in a regulatory authority

Group of Experts No. 14 (Radiopharmaceutical Preparations)

Terms of reference

- Drafting and revision of monographs allocated to the group by the Commission in the field of radiopharmaceutical preparations

Profile for experts

- Current expertise in pharmaceutical analytical methods, related to quality control of radiopharmaceutical preparations and in development of control methods
- Access to laboratory facilities for verification of methods proposed for inclusion in monographs, **Essential**: Active involvement in drafting of texts and laboratory verification of test methods
- 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
    - Method development and verification in a regulatory authority

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

Terms of reference

- Drafting and revision of monographs allocated to the group by the Commission in the field of vaccines and sera for human use
- Drafting and revision of monographs allocated to the group by the Commission in the field of botulinum toxins

Profile for experts

- Current expertise in analytical methods, related to quality control of vaccines and sera for human use and in development of control methods
- 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 methods for botulinum toxins and in development of control methods
- 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 control methods for botulinum toxins in a research and development environment

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

Terms of reference

- Drafting and revision of monographs allocated to the group by the Commission in the field of immunological veterinary medicinal products (IVMP)

Profile for experts

- Current expertise in suitable standards for IVMP, in methods related to quality control of these products and in development of control methods
- 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 methods 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 general chapters allocated to the working party by the Commission 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 of methods proposed for inclusion in general chapters, **Essential**: Active involvement in drafting of texts and laboratory verification of test methods
- 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
  - Quality control of plastic materials, plastic containers and closures in a regulatory authority
  - Assessment of the relevant parts of applications for marketing authorisation within a medicines agency
  - Quality control of plastic materials, plastic containers and closures in an independent testing laboratory
  - Method development and verification in a regulatory authority

Group of Experts P4

Terms of reference

- Drafting and revision of monographs allocated to the group by the Commission in the field of single-source active substances, excipients and finished products with chemically defined active substances

Profile for experts

- Current expertise in pharmaceutical analytical methods, related to quality control of active substances, excipients and finished products (with chemically defined active substances), and in development of control methods
- Access to laboratory facilities for verification of methods proposed for inclusion in monographs or access to licensing files, **Essential**: Active involvement in drafting of texts and laboratory verification of test methods
- 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
    - Method 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)

Objective

- Drafting and revision of monographs and general chapters allocated to the group by the Commission in the field of allergen products

Profile for experts

- Current expertise in pharmaceutical analytical methods, related to quality control of allergens and in development of control methods
- 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 methods for control of allergens in a research and development environment

BET Working Party (Bacterial Endotoxin Test)

Terms of reference

- International Harmonisation of monographs and general chapters as decided by the Commission
- Drafting and revision of general chapters allocated to the group by the Commission in the field of bacterial endotoxins
- Advising the Commission on acceptance criteria for bacterial endotoxins to be included in monographs, in accordance with the **European Pharmacopoeia policy on bacterial endotoxins in substances for pharmaceutical use,** *Approved by the European Pharmacopoeia Commission at its 149th Session, June 2014* (http://pharmeuropa.edqm.eu/home/menupage/English/Useful%20Information/Ph_Eur_policy_for_Pharmeuropa_E.pdf)
- Drafting and revision of general chapters allocated to the group by the Commission in the field of the monocyte activation tests (MAT)

Profile for experts

- 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 control methods for bacterial endotoxin test in a research and development environment

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

- Current expertise in practical application of the monocyte activation test
- Access to laboratory facilities for verification of methods proposed for inclusion in monographs,
- 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 control methods for monocyte activation test in a research and development environment
    - Method development and verification in a regulatory authority

CE Working Party (Capillary Electrophoresis)

Terms of reference

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

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 capillary electrophoresis methods for control of active substances, excipients and medicinal products in a research and development environment or at university
    - **Essential**: Active involvement in drafting of texts and laboratory verification of test methods

CEL Working Party (Cellulose)

Terms of reference

- Drafting and revision of monographs allocated to the group by the Commission on cellulose and cellulose derivatives
- International harmonisation of monographs on cellulose and cellulose derivatives as decided by the Commission

Profile for experts

- Current expertise in analytical methods for cellulose and cellulose derivatives and in development of control methods
- Access to laboratory facilities for verification of methods proposed for inclusion in monographs, **Essential**: Active involvement in drafting of texts and laboratory verification of test methods
- 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 control methods for cellulose and cellulose derivatives in a research and development environment
    - Method development and verification in a regulatory authority

CND Working Party (Conductivity)

Terms of reference

- International harmonisation of 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 methods for conductivity measurement in a research and development environment

COL Working Party (Colour determination)

Terms of reference

- Drafting and revision of monographs and texts allocated to the Working Party by the Commission 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 allocated to the group by the Commission in the field of carbohydrates
- International harmonisation of monographs

Profile for experts

- Current expertise in pharmaceutical analytical methods, related to quality control of carbohydrates and in development of control methods
- Access to laboratory facilities for verification of methods proposed for inclusion in monographs, **Essential**: Active involvement in drafting of texts and laboratory verification of test methods
- 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 control methods for carbohydrates in a research and development environment
  - Method development and verification in a regulatory authority

CST Working Party (Chromatographic separation techniques)

Terms of reference

- Revision of the chapter *2.2.46 Chromatographic separation techniques* as decided by the Commission
- Revision of other chapters on chromatographic separation (e.g. 2.2.29, 2.2.30) as decided by the Commission
- International harmonisation of chapter 2.2.46 (PDG item G-20)

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 methods 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

- Revision of general chapter *2.6.27 Microbiological control of cellular products* allocated to the group by the Commission
- Elaboration of a general text dealing with microbiological control of organs and tissues for human use, including preservation and other related media (e.g. sampling, deswelling media)

Profile for experts

- Current expertise in analytical methods, related to development and quality control of cell therapy products and/or tissue-engineered products and/or to quality control of organs and tissues for human use, and in development of microbiological control methods
- Several years of experience in one or more of the following fields:
  - Development of cell therapy products and/or tissue-engineered products
  - Microbiological 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 microbiological quality of cell therapy products, tissue-engineered products and/or tissues and organs used for human transplantation in a regulatory authority
  - Microbiological quality control of cell therapy products, tissue-engineered products and/or tissues and organs used for human transplantation in an independent testing laboratory
  - Development of methods for microbiological control of cell therapy products, 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 monographs and general chapters allocated to the working party by the Commission in the field of preparations for dialysis

Profile for experts

- Current expertise in the fields covered by the terms of reference

- Access to laboratory facilities for verification of methods proposed for inclusion in monographs
- Several years of experience in one or more of the following fields:
    - 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
    - Method development and verification in a regulatory authority

EXP Working Party (Excipient performance)

Terms of reference

- Evaluation of the *excipient performance* (in line with the ICH Q8 guideline), in view of revising to reflect current best practices, as appropriate, and maintaining the FRC (Functionality related Characteristics) sections of monographs on excipients, 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 methods (including in the Ph Eur section 2.09 Pharmaceutical technical procedures), related to control of excipients and in development of control methods
- Several years of experience in one or more of the following fields:
    - Quality control of excipients in a bulk or pharmaceutical manufacturing setting
    - Pharmaceutical research and development
    - Assessment of the relevant parts of applications for marketing authorisation within a medicines agency
    - Development of control methods for determination of excipient performance (FRCs) in a research and development environment
    - Pharmaceutical quality control in an independent testing laboratory

EXT Working Party (Extracts)

Terms of reference

- Revision of the general monograph on *Extracts (0765)* with the aim of clarifying/improving the definitions and requirements of the different types of extracts whilst maintaining the established classification system of 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
- International harmonisation of monographs on Gelatin

Profile for experts:

- Current expertise in pharmaceutical analytical methods, related to quality control of gelatin and in development of control methods
- 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
    - Method development and verification in a regulatory authority
    - Development of pharmaceutical control methods using near infrared spectrometry for gelatin identification

GLS Working Party (Glass Containers)

Terms of reference

- Drafting and revision of general chapters allocated to the group by the Commission in the field of glass containers

Profile for experts

- Current expertise in the production of glass containers, analytical methods, related to quality control of glass containers and in development of control methods
- Access to laboratory facilities for verification of methods proposed for inclusion in monographs
- 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 control methods for control of glass containers in a research and development environment

HM Working Party (Heavy metals)

Terms of reference

- Drafting of a general chapter to implement the future ICH Q3D guideline on metal 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 methods, 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 allocated to the group by the Commission 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 monographs allocated to the group by the Commission in the field of homoeopathic raw materials and stocks

Profile for experts

- Current expertise in pharmaceutical analytical methods, related to quality control of homoeopathic raw materials and stocks and in development of control methods
- Access to laboratory facilities for verification of methods proposed for inclusion in monographs, Essential: Active involvement in drafting of texts and laboratory validation and verification of test methods
- 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 methods for control of homoeopathic raw materials and stocks in a research and development environment
    - Method development and verification in a regulatory authority

ICP Working Party (Inductively-Coupled Plasma)

Terms of reference

- Drafting and revision of general methods allocated to the working party by the European Pharmacopoeia Commission 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 allocated to the group by the Commission in the field of preparations for inhalation
- International harmonisation of general chapters as decided by the Commission

Profile for experts

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

LBP Working Party (Live Biotherapeutic Products)

Terms of reference

Elaboration of a monograph on Live Biotherapeutic Products, allocated to the Working Party by the Commission. Live Biotherapeutic Products (LBP) to be considered in the scope are biological medicinal products that contains live micro-organisms such as bacteria or yeast. A LBP may be administered orally, vaginally or intravesically.

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

- Drafting and revision of monographs allocated to the group by the Commission in the field of lecithins

Profile for experts

- Current expertise in pharmaceutical analytical methods, related to quality control of lecithins and in development of control methods
- Access to laboratory facilities for verification of methods proposed for inclusion in monographs, **Essential**: Active involvement in drafting of texts and laboratory verification of test methods
- 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 control methods for lecithins in a research and development environment
  - Method 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 product specific monographs using the multisource approach (according to document PA/PH/Exp. MAB/T (14) 1)
- Drafting and revision of monographs and general chapters allocated to the group by the Commission in the field of monoclonal antibodies
- Support to the Secretariat in case of questions raised by e.g. users in the field of monoclonal antibodies

Profile for experts

- Current expertise in pharmaceutical analytical methods, related to quality control of monoclonal antibodies and in development of control methods
- Access to laboratory facilities for verification of methods proposed for inclusion in monographs or access to licensing files. **Essential**: Active involvement in drafting of texts and laboratory verification of test methods
- 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 control methods 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

In reference to the concept paper prepared by the Secretariat and presented to the Ph. Eur. Commission at its 149th session (see PA/PH/SG (14) 29):

- Make concrete proposals to the Commission, on the best approaches to tackle the revision needs of general methods
- Reflect on the content and the degree of details to be provided in general methods in view of drafting a guide for the elaboration of general methods at a later stage

Profile for experts

- Members of OMCLs, national pharmacopoeia authorities, licensing authorities, universities or the pharmaceutical/chemical industries
- Current expertise and extensive knowledge in compendial methods and/or instruments used in the quality control of active substances, excipients and/or medicinal products and in development of control methods
- Several years of experience in one or more of the following fields:
    - Method development and verification in e.g. analytical or pharmaceutical development, a regulatory authority, an independent 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

NBC Working Party (Non-Biological Complexes)

Terms of reference

- Elaboration and revision of monographs on non-biological complexes (e.g. nanoparticle solutions, like for example iron sucrose concentrated solution) allocated to the group by the Commission

Profile for experts

- Current expertise in the development and/or quality control of non-biological complexes and in development of control methods
- Access to laboratory facilities for verification of methods proposed for inclusion in monographs, **Essential**: Active involvement in drafting of texts and laboratory verification of test methods
- Several years of 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)
    - Pharmaceutical and/or analytical development related to respective formulations
    - Assessment of the relevant parts of applications for marketing authorisation within a medicines agency

P4BIO Working Party (P4 Bio) Pilot phase

Terms of reference

- Drafting and revision of monographs allocated to the group by the Commission 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 methods, related to quality control of biologicals and in development of control methods
- Access to laboratory facilities for verification of methods proposed for inclusion in monographs or access to licensing files (essentially originating from CAP), **Essential**: Active involvement in drafting of texts and laboratory verification of test methods
- 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 (PaedForm)

Terms of reference

In reference to the document "Implementation of a pan-European Paediatric Formulary (PaedForm)" (see PA/PH/SG (13) 45 1R) approved by the Ph. Eur. Commission at its 147th session:

- 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 of paediatric preparations (including toxicologists)
- Current expertise in analytical methods related to quality control of ingredients (APIs and excipients) and preparations and in the development of such methods; Access to laboratory facilities for verification of methods 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)
- Method 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 of existing pharmacopoeial texts in view of needs arising from Process Analytical Technology (PAT), 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

Profile for experts

- Expertise in chemical or pharmaceutical development and control methods 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, RTRT or QbD concepts in an industrial setting
  - Assessment of the relevant parts of applications for marketing authorisation containing PAT, RTRT or QbD concepts within a medicines agency
  - Development of control strategies including PAT, 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 (Powders)

Terms of reference

- Drafting and revision of general chapters allocated to the group by the Commission in the field of powder characterisation
- International harmonisation of general chapters as decided by the Commission

Profile for experts

- Current expertise in methods for powder characterisation, related to quality control of active substances and excipients and in development of control methods
- 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 methods 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 monographs allocated in the field of non-radioactive precursors for radiopharmaceutical preparations

Profile for experts

- Expertise in chemical, pharmaceutical and radiopharmaceutical methods, related to quality control of radiopharmaceutical preparations and their precursors
- Access to laboratory facilities for verification of methods proposed for inclusion in monographs. **Essential**: Active involvement in drafting of texts and laboratory verification of test methods
- 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 general chapters allocated to the group by the Commission in the field of pesticide residues
- Advising the Commission on acceptance criteria for pesticide residues to be included in monographs
- Maintenance of the list of pesticides tabled in general chapter on pesticide residues

Profile for experts

- Current expertise in pesticide analysis, related to quality control of active substances and excipients and in development of control methods
- Access to laboratory facilities for verification of methods 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 control methods for analysis of pesticide residues in a research and development environment

ROP Working Party (Rules of Procedure)

Terms of reference

Revision of the Rules of procedure of the European Pharmacopoeia Commission, of the Guide for work of the European Pharmacopeia and of the Code of practice, as agreed by the Commission

Profile for experts

Members of national pharmacopoeia authorities of a Ph. Eur. Member states or delegations to the European Pharmacopoeia Commission The ROP WP is chaired by the Chair of the Ph. Eur. Commission

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, as needed.

Propose to the Commission further items for the work programme (such as replacements of methods not in line with the available instrumentation in pharmacies or monographs with missing second identification)

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 methods commonly available in pharmacies
- Members of regulatory authorities (e.g. National Pharmacopoeia Authorities, OMCLs)

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 ~~containers~~ 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 regulatory authorities (such as National Pharmacopoeia Authorities, medicines agencies), universities

SUT Working Party (Sutures)

Terms of reference

- Drafting and revision of monographs allocated to the group by the Commission in the field of sutures

Profile for experts

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

TCM Working Party (Traditional Chinese Medicines)

Terms of reference

- Drafting and revision of monographs allocated to the group by the Commission in the field of herbal drugs and herbal drug preparations preferably based on the principle of adapting/improving existing monographs or methods 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 methods, related to quality control of herbal drugs and herbal drug preparations and in development of control methods
- Access to laboratory facilities for verification of methods 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 of methods for control of herbal drugs
- Involvement in market surveillance or regulatory oversight of imported TCM herbal drugs

- **Essential**: Active involvement in drafting of texts and laboratory verification of test methods for TCM herbal drugs
- Development of chromatographic separation systems for herbal drug constituents
- Knowledge in cultivation, harvesting, processing and use of TCM herbal drugs

VIT Working Party (Vitamins)

Terms of reference

- Drafting and revision of monographs allocated to the group by the Commission in the field of vitamins and vitamin derivatives

Profile for experts

- Current expertise in pharmaceutical analytical methods, related to quality control of vitamins and excipients and in development of control methods. *The need of a specialist for vitamin D type substances is highlighted*
- Access to laboratory facilities for verification of methods proposed for inclusion in monographs, **Essential**: Active involvement in drafting of texts and laboratory verification of test methods
- 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 methods for control of vitamins in a research and development environment
  - Method development and verification in a national pharmacopoeia laboratory

VSADM Working party (Vibrational Spectroscopy and Analytical Data Modelling)

Terms of reference

- Drafting and revision of general chapters allocated to the group by the Commission in the field of:
  - Chemometrics, i.e. modelling of analytical data (e.g. Multivariate Data analysis , Data mining, Chemical imaging etc.)
  - measurement techniques relying extensively on analytical data modelling (NIR, RAMAN) or other vibrational spectroscopies (IR)
  - provide support to the PAT WP where PAT/ QbD elements of the above mentioned chapters are concerned

Profile for experts

- Current expertise vibrational spectroscopy related to quality control of active substances and excipients and in development of control methods
- Several years of experience in one or more of the following fields:
  - Use of near infrared spectrometry and other vibrational spectroscopic techniques for quality control in a pharmaceutical manufacturing setting
  - Development of pharmaceutical control methods using near infrared spectrometry and other vibrational spectroscopic techniques or chemometrics in a research and development environment
  - Assessment of applications for marketing authorisation
  - Market surveillance of quality in of texts
  - Pharmaceutical quality control in an independent testing laboratory

WAT Working Party (Water)

Terms of reference

- Drafting and revision of monographs and general chapters allocated to the group by the Commission in the field of water
- International harmonisation of monographs and general chapters as decided by the Commission

Profile for experts

- Current expertise in analytical methods applicable in water analysis in development of control methods
- 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 methods for control of pharmaceutical waters in a research and development environment