Group of Experts No. 1 (Microbiology)

2 Terms of reference

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- 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)

11 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
 - o Market surveillance of microbiological quality in a regulatory authority
 - o Assessment of the relevant parts of applications for marketing authorisation
 - o Development of microbiological control methods in a research and development environment

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

- 21 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
- 26 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

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

- 41 Terms of reference
 - Drafting and revision of general chapters and monographs allocated to the group by the Commission in the field of blood products
- 44 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, 1 Essential: Active involvement in drafting of texts and laboratory verification of test methods 2 Several years of experience in one or more of the following fields: 3 Quality control of blood products in a pharmaceutical or bulk manufacturing setting 4 Batch release or market surveillance of Human Blood, Plasma and Plasma Products in a 5 regulatory authority 6 Assessment of the relevant parts of applications for marketing authorisation within a medicines 7 8 Quality control of blood products in an independent testing laboratory 9 Development of methods for control Human Plasma and Plasma Products in a research and 10 development environment 11 Group of Experts No. 7 (Antibiotics) 12 Terms of reference 13 Drafting and revision of monographs and general chapters allocated to the group by the Commission in 14 the field of antibiotics (active substances and/or finished products if / when allocated to the group by the 15 Commission) 16 17 Profile for experts Current expertise in the fields covered by the terms of reference 18 Access to laboratory facilities for verification of methods proposed for inclusion in monographs, 19 Essential: Active involvement in drafting of texts and laboratory verification of test methods 20 Several years of experience in one or more of the following fields: 21 Quality control of antibiotics (active substances and/or finished products) in a pharmaceutical 22 manufacturing setting 23 Quality control of antibiotics (active substances and/or finished products) in a bulk 24 manufacturing setting 25 Quality control of antibiotics (active substances and/or finished products) in a regulatory 26 27 authority Assessment of the relevant parts of applications for marketing authorisation within a medicines 28 29 Quality control of antibiotics (active substances and/or finished products) in an independent 30 testing laboratory 31 Development of methods for control of antibiotics in a research and development environment 32 Method development and verification in a regulatory authority 33 Group of experts No. 9 (Inorganic Chemistry) 34 35 Terms of reference Drafting and revision of monographs allocated to the group by the Commission in the field of inorganic 36 37 International harmonisation of monographs where decided by the Commission 38 39 Profile for experts Current expertise in pharmaceutical analytical methods, related to quality control of inorganic active 40 substances and excipients and in development of control methods 41 Access to laboratory facilities for verification of methods proposed for inclusion in monographs, for 42 example ICP and/or AAS. Essential: Active involvement in drafting of texts and laboratory verification 43 of test methods 44 Several years of experience in one or more of the following fields: 45 Quality control inorganic active substances and excipients in a pharmaceutical or bulk 46 manufacturing setting 47

Market surveillance of quality in a regulatory authority

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1	 Pharmaceutical quality control in an independent testing laboratory
2 3	 Development of methods for control of inorganic products in a research and development environment
4	 Method development and verification in a national pharmacopoeia laboratory
5	Group of Experts No. 9G (Medicinal Gases)
6	Terms of reference
7	 Drafting and revision of monographs and general chapters allocated to the group by the Commission in
8	the field of medicinal gases
9	Profile for experts
10	 Current expertise in the fields covered by the terms of reference
11 12	 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
13	 Several years of experience in one or more of the following fields:
14 15	 Quality control of medicinal gases in a pharmaceutical manufacturing, hospital or industrial setting
16	 Quality control in a regulatory authority
17	o Development of methods for control of medicinal gases in a research and development
18	environment
19	Group of Experts No. 10A/B/C/D (Organic chemistry – synthetic and semi-synthetic products)
20	Terms of reference
21 22	 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
23 24	 Drafting and revision of finished product monographs with chemically defined active substance if / when allocated to the group by the Commission
25	Profile for experts
26 27 28	 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
29 30	 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
31	 Several years of experience in one or more of the following fields:
32	 Quality control in a pharmaceutical manufacturing setting
33 34	 Quality control of synthetic and semi-synthetic organic products in a bulk manufacturing setting
35	 Market surveillance of quality in a regulatory authority
36 37	 Pharmaceutical quality control of active substances, excipients and /or finished products with chemically defined active substances in an independent testing laboratory
38 39	 Development of methods for control of active substances, excipients and /or finished products with chemically defined active substances in a research and development environment
40	 Group 10D: development of control methods for amino-acids
41	 Method development and verification in a regulatory authority
42	Group of Experts No. 11 (Organic chemistry – natural, semi-synthetic and synthetic products)
43	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 1 Current expertise in pharmaceutical analytical methods, related to quality control of active substances, 2 excipients and finished products and in development of control methods 3 Access to laboratory facilities for verification of methods proposed for inclusion in monographs, 4 Essential: Active involvement in drafting of texts and laboratory verification of test methods 5 Several years of experience in one or more of the following fields: 6 Quality control in a pharmaceutical manufacturing setting 7 Quality control of natural, semi-synthetic and synthetic organic products (active substances, 8 excipients and/or finished products) in a bulk manufacturing setting 9 Market surveillance of quality in a regulatory authority 10 Pharmaceutical quality control in an independent testing laboratory 11 O Development of methods for control of active substances and /or excipients and/or finished 12 products in a research and development environment 13 Method development and verification in a regulatory authority 14 Group of Experts No. 12 (Dosage forms and dosage form methods) 15 Terms of reference 16 Drafting and revision of dosage form monographs 17 Maintenance of dosage form related International Harmonisation topics such as: 18 uniformity of dosage units 19 dissolution 20 disintegration 21 particulate contamination: sub-visible particles 22 23 Profile for experts Current expertise in pharmaceutical development and control methods applied during manufacture and 24 to finished pharmaceutical preparations, in the relevant specialities defined in the terms of reference 25 Several years of experience in one or more of the following fields: 26 Development and quality control of pharmaceutical preparations in an industrial setting 27 Assessment of the relevant parts of applications for marketing authorisation within a medicines 28 29 agency Development of methods for testing of pharmaceutical preparations in a research and 30 development environment 31 Method development and verification in a regulatory authority 32 Group of Experts No. 13A/B (Herbal Drugs and Herbal Drug Products) 33 34 Terms of reference Drafting and revision of monographs allocated to the group by the Commission in the field of herbal 35 drugs and herbal drug preparations 36 37 Profile for experts Current expertise in pharmaceutical analytical methods, related to quality control of herbal drugs and 38 herbal drug preparations and in development of control methods 39 Access to laboratory facilities for verification of methods proposed for inclusion in monographs, 40 Essential: Active involvement in drafting of texts and laboratory verification of test methods 41 Several years of experience in one or more of the following fields: 42 Quality control of herbal drugs and herbal drug preparations in a pharmaceutical 43 manufacturing or bulk manufacturing setting 44 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

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1 2		 Pharmaceutical quality control of herbal drugs and herbal drug preparations in an independent testing laboratory
3		o Development of methods for control of herbal drugs in a research and development
4		environment
5		 Method development and verification in a regulatory authority
6	Group	of Experts No. 13H (Fatty oils and derivatives, polymers)
7	Terms	of reference
8 9	•	A panel of Specialists is appointed for the drafting and revision of monographs allocated to the group by the Commission in the field of:
10		o surfactants
11		o fatty oils, fats and waxes
12		o fatty acids, fatty alcohols and their esters/ethers
13		 macrogols, macrogol derivatives and other polymers (i.e. carbomers)
14		o Paraffins
15	•	International Harmonisation of the relevant monographs
16	Profile	for experts
17 18	•	Current expertise in pharmaceutical analytical methods, related to quality control in the relevant specialities defined in the terms of reference
19 20	•	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
21	•	Several years of experience in one or more of the following fields:
22		 Quality control in a pharmaceutical manufacturing setting
23		 Quality control of fats etc. in a bulk manufacturing setting
24		 Market surveillance of quality in a regulatory authority
25		 Pharmaceutical quality control of fats etc. in an independent testing laboratory
26		 Development of methods for control of fats etc. in a research and development environment
27		 Method development and verification in a regulatory authority
28	Group	of Experts No. 14 (Radiopharmaceutical Preparations)
29	Terms o	of reference
30 31	•	Drafting and revision of monographs allocated to the group by the Commission in the field of radiopharmaceutical preparations
32	Profile	for experts
33 34	•	Current expertise in pharmaceutical analytical methods, related to quality control of radiopharmaceutical preparations and in development of control methods
35 36	•	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
37	•	Several years of experience in one or more of the following fields:
38 39		 Quality control of radiopharmaceutical preparations in a pharmaceutical manufacturing setting or in a hospital
40		 Market surveillance of quality of radiopharmaceutical preparations in a regulatory authority
41		 Assessment of the relevant parts of applications for marketing authorisation within a medicines
42		agency
43 44		 Pharmaceutical quality control of radiopharmaceutical preparations in an independent testing laboratory
45		 Method development and verification in a regulatory authority

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

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- 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:
 - O 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
 - O Quality control of vaccines and sera for human use in an independent testing laboratory

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

18 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
 - o 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

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1 2		 Quality control of plastic materials, plastic containers and closures in an independent testing laboratory
3		 Method development and verification in a regulatory authority
4	BET V	orking Party (Bacterial Endotoxin Test)
5	Terms of	of reference
6	•	International Harmonisation of monographs and general chapters as decided by the Commission
7 8	•	Drafting and revision of general chapters allocated to the group by the Commission in the field of bacterial endotoxins
9 10	•	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
11 12		pharmaceutical use, Approved by the European Pharmacopoeia Commission at its 149th Session, June 2014
13 14		(http://pharmeuropa.edqm.eu/home/menupage/English/Useful%20Information/Ph Eur policy for Pharmeuropa E.pdf)
15 16	•	Drafting and revision of general chapters allocated to the group by the Commission in the field of the monocyte activation tests (MAT)
17	Profile	for experts
18	•	Several years of experience in one or more of the following fields:
19		o Quality control of parenteral preparations, active substances and/or excipients in a
20		pharmaceutical manufacturing setting
21		 Market surveillance of quality in a regulatory authority
22		 Pharmaceutical quality control in an independent testing laboratory
23 24		 Development of control methods for bacterial endotoxin test in a research and development environment
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26	CE Wo	rking Party (Capillary Electrophoresis)
27	Terms o	of reference
28	•	Revision of the chapter 2.2.47 Capillary electrophoresis as decided by the Commission
29 30	•	Advising the Commission on questions related to capillary electrophoresis in monographs drafted by other groups of experts and working parties
31	Profile.	for experts
32	•	Current expertise in Capillary electrophoresis techniques
33	•	Several years of experience in the following fields:
34		O Quality control of active substances, excipients and medicinal products, using capillary
35 36		electrophoresis techniques, in a pharmaceutical manufacturing setting, in a regulatory authority or in any other testing laboratory
37 38		 Development of capillary electrophoresis methods for control of active substances, excipients and medicinal products in a research and development environment or at university
39		o Essential: Active involvement in drafting of texts and laboratory verification of test methods
40	CEL W	orking Party (Cellulose)
41	Terms o	f 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 1 Current expertise in analytical methods for cellulose and cellulose derivatives and in development of 2 control methods 3 Access to laboratory facilities for verification of methods proposed for inclusion in monographs, 4 Essential: Active involvement in drafting of texts and laboratory verification of test methods 5 Several years of experience in one or more of the following fields: 6 Quality control of cellulose and cellulose derivatives in a pharmaceutical or other industrial 7 8 manufacturing setting Market surveillance of quality of cellulose and cellulose derivatives in a regulatory authority 9 Quality control of cellulose and cellulose derivatives in a regulatory authority 10 Development of control methods for cellulose and cellulose derivatives in a research and 11 development environment 12 Method development and verification in a regulatory authority 13 CLAR Working Party (Clarity and degree of opalescence of liquids) 14 15 Terms of reference To evaluate the request for revision related to chapter 2.2.1 Clarity and degree of opalescence of liquids and to 16 revise, if applicable, the corresponding chapter. 17 Profile for experts 18 Current expertise in pharmaceutical analytical methods, related to the control of Clarity and degree of 19 opalescence of liquids in development of control methods 20 Several years of experience in one or more of the following fields: 21 Quality control applying one or more methods as described in chapter 2.2.1 22 Market surveillance of quality in a regulatory authority 23 **CND Working Party (Conductivity)** 24 25 Terms of reference International harmonisation of general chapter 2.2.38 Conductivity 26 27 Profile for experts Current expertise in conductivity measurement 28 Several years of experience in one or more of the following fields: 29 Quality control using conductivity measurement in a pharmaceutical manufacturing setting 30 Market surveillance of quality using conductivity measurement in a regulatory authority 31 Conductivity measurement for pharmaceutical analysis in an independent testing laboratory 32 Conductivity measurement in a regulatory authority 33 Development of methods for conductivity measurement in a research and development 34 35 environment **COL Working Party (Colour determination)** 36 Terms of reference 37 Drafting and revision of monographs and texts allocated to the Working Party by the Commission in the 38 field of instrumental determination of colour (PDG item Q-07) 39 Establishing correlation between measurement using Ph. Eur. Chapter 2.2.2 and the tristimulus type 40

instruments

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

Profile for experts

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- Users: Expertise in the use of tristimulus-type of colour measuring instruments in the field of 1 2 pharmaceutical development, quality control of pharmaceuticals, food, cosmetics or drinking 3 Instrument suppliers: Personnel involved in user-support for practical application of 4 tristimulus-type instruments in the field of pharmaceutical development, quality control of 5 6 pharmaceuticals, food, cosmetics or drinking water 7 Experience in research or university teaching related to instrumental colour determination of 8 liquids 9 **CRB Working Party (Carbohydrates)** 10 Terms of reference Drafting and revision of monographs allocated to the group by the Commission in the field of 11 12 carbohydrates International harmonisation of monographs 13 14 Profile for experts 15 Current expertise in pharmaceutical analytical methods, related to quality control of carbohydrates and 16 in development of control methods Access to laboratory facilities for verification of methods proposed for inclusion in monographs, 17 18 Essential: Active involvement in drafting of texts and laboratory verification of test methods 19 Several years of experience in one or more of the following fields: 20 Quality control in a pharmaceutical or bulk manufacturing setting Market surveillance of quality in a regulatory authority 21 22 Pharmaceutical quality control in an independent testing laboratory 23 Development of control methods for carbohydrates in a research and development 24 environment Method development and verification in a regulatory authority 25 26 CST Working Party (Chromatographic separation techniques) 27 Terms of reference 28 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 29 30 Commission International harmonisation of chapter 2.2.46 (PDG item G-20) 31 32 Profile for experts 33 Current expertise in chromatographic separation techniques 34 Several years of experience in one or more of the following fields: 35 Chromatographic quality control of active substances and/or excipients in a pharmaceutical 36 manufacturing setting 37 Development of chromatographic methods for control of active substances, excipients and 38 medicinal products in a research and development environment 39 Market surveillance of quality in a regulatory authority 40 Pharmaceutical quality control in an independent testing laboratory 41 **CTP Working Party (Cell Therapy Products)** 42 Terms of reference

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- 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)

HM Working Party (Heavy metals)

Terms of reference 2

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- 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
 - 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 22

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
- Several years of experience in one or more of the following fields:
 - Quality control of homoeopathic raw materials and stocks in a pharmaceutical manufacturing
 - Assessment of applications for marketing authorisation of homoeopathic products within an 0
- 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:
o development of Live Biotherapeutic Products
o production of Live Biotherapeutic Products
o 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)

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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
- 12 o 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
- 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)

37 Terms of reference

In reference to the concept paper prepared by the Secretariat and presented to the Ph. Eur. Commission at its 149th session:

- 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

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- 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
 - o 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)

- 15 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)
 - o Pharmaceutical and/or analytical development related to respective formulations
 - Assessment of the relevant parts of applications for marketing authorisation within a medicines agency

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
- 36 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

1 2		 Development of pharmaceutical preparations using PAT, RTRT or QbD concepts in an industrial setting
3		 Assessment of the relevant parts of applications for marketing authorisation containing PAT, RTRT or QbD concepts within a medicines agency
5		 Development of control strategies including PAT, RTRT or QbD concepts approaches for testing of active substances or pharmaceutical preparations
7		 Development of pharmaceutical preparations using modelling and chemometrics associated with the analytical aspects for PAT
9	POW W	orking Party (Powders)
10	Terms o	f reference
11 12	•	Drafting and revision of general chapters allocated to the group by the Commission in the field of powder characterisation
13	•	International harmonisation of general chapters as decided by the Commission
14	Profile 1	for experts
15 16	•	Current expertise in methods for powder characterisation, related to quality control of active substances and excipients and in development of control methods
17	•	Several years of experience in one or more of the following fields:
18		 Quality control of active substances and excipients in a pharmaceutical manufacturing setting
19		 Assessment of the relevant parts of applications for marketing authorisation
20		Market surveillance of quality in a regulatory authority
21 22		 Development of methods for characterisation of powders in a research and development environment
23		 Pharmaceutical quality control in an independent testing laboratory
24	PRP W	orking Party (Precursors for Radiopharmaceutical Preparations)
25	Terms o	f reference
26 27	•	Drafting and revision of monographs allocated in the field of non-radioactive precursors for radiopharmaceutical preparations
28	Profile	for experts
29 30	•	Expertise in chemical, pharmaceutical and radiopharmaceutical methods, related to quality control of radiopharmaceutical preparations and their precursors
31 32	•	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
33	•	Several years of experience in one or more of the following fields:
34		 Ouality control of radiopharmaceutical preparations and their precursors
35		 Quality control of synthetic organic and/or inorganic products in a chemical or pharmaceutical setting
36		Quity and in an independent tecting laboratory
37 38		 Quality control in an independent testing laboratory Development of analytical procedures for the control of radiopharmaceutical preparations and
39		their precursors
40	PST V	orking Party (Pesticide Residues)
41	Terms	of reference
42 43	•	Drafting and revision of general chapters allocated to the group by the Commission in the field of nesticide residues
44	•	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

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- 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
 - o Pharmaceutical quality control in an independent testing laboratory
- Development of control methods for analysis of pesticide residues in a research and development environment

SIT Working Party (Second identification test)

13 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)

19 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)

26 SRP Working Party (Special Revision Programme)

27 Terms of reference

 Review of revision proposals for the related substances tests and limits in monographs allocated to the group by the Commission in the field of active substances

30 Profile for experts

- Current expertise in pharmaceutical analytical methods, related to quality control of active substances and excipients and in development of control methods
- 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
 - o Market surveillance of quality in a regulatory authority
 - Method 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.

43 ST Working Party (Standard Terms)

44 Terms of reference

 Development of standard terms for dosage forms, routes of administration, containers at the request of Competent authorities of Member States or EMA

Profile for experts 1 Current expertise in pharmaceutical dosage forms 2 Several years of experience in one or more of the following fields: 3 Assessment of the pharmaceutical development part of applications for authorisation of 4 medicinal products 5 Development of general monographs for dosage forms (group of experts or national 6 pharmacopoeia secretariat) 7 Experience in formulation of medicinal products 8 Members of the working party may be from regulatory authorities (such as National Pharmacopoeia 9 Authorities, medicines agencies), universities 10 **STA Working Party (Statistics)** 11 Terms of reference 12 Drafting and revision of general chapters allocated to the group by the Commission in the field of 13 statistical analysis 14 Advising the Commission on questions related to statistics in the context of monograph elaboration by 15 appropriate Groups of Experts 16 Profile for experts 17 Current expertise in statistical analysis, related to quality control of active substances, excipients and 18 medicinal products 19 Several years of experience in one or more of the following fields: 20 Statistical analysis of results of control tests in a pharmaceutical manufacturing setting 21 Development of statistical methods applied in pharmaceutical analysis 22 **SUT Working Party (Sutures)** 23 Terms of reference 24 Drafting and revision of monographs allocated to the group by the Commission in the field of sutures 25 26 Profile for experts Expertise in pharmaceutical analytical methods, related to quality control of sutures and in development 27 of control methods 28 Several years of experience in one or more of the following fields: 29 Quality control of sutures 30 Development of methods for control of sutures 31 TCM Working Party (Traditional Chinese Medicines) 32 33 Terms of reference Drafting and revision of monographs allocated to the group by the Commission in the field of herbal 34 drugs and herbal drug preparations preferably based on the principle of adapting/improving existing 35 monographs or methods to control herbal drugs used in Traditional Chinese Medicines (TCM) 36 Drafting general chapters related to the specific needs of TCM herbal drugs 37 Profile for experts 38 Current expertise in pharmaceutical analytical methods, related to quality control of herbal drugs and 39 herbal drug preparations and in development of control methods 40 Access to laboratory facilities for verification of methods proposed for inclusion in monographs 41 Several years of experience in one or more of the following fields: 42 Quality control of herbal drugs/herbal drug preparations in a manufacturing setting 43

Pharmaceutical quality control of herbal drugs and herbal drug preparations in an independent

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testing laboratory

1	 Development of methods for control of herbal drugs 	
2	 Involvement in market surveillance or regulatory oversight of imported TCM herbal drugs 	
3	 Essential: Active involvement in drafting of texts and laboratory verification of test methods for Toherbal drugs 	CM
5	Development of chromatographic separation systems for herbal drug constituents	
6	 Knowledge in cultivation, harvesting, processing and use of TCM herbal drugs 	
7	VIT Working Party (Vitamins)	
8	Terms of reference	
9 10	 Drafting and revision of monographs allocated to the group by the Commission in the field of vitam and vitamin derivatives 	nins
11	Profile for experts	
12 13 14	 Current expertise in pharmaceutical analytical methods, related to quality control of vitamins and in development of control methods. The need of a specialist for vitamin D to substances is highlighted 	
15 16	 Access to laboratory facilities for verification of methods proposed for inclusion in monograp Essential: Active involvement in drafting of texts and laboratory verification of test methods 	hs,
17	 Several years of experience in one or more of the following fields: 	
18	 Quality control of vitamins in a pharmaceutical or bulk manufacturing setting 	
19	 Market surveillance of quality in an official control laboratory for medicines 	
20	 Pharmaceutical quality control in an independent testing laboratory 	
21	 Development of methods for control of vitamins in a research and development environmen 	t
22	 Method development and verification in a national pharmacopoeia laboratory 	
23	VSADM Working party (Vibrational Spectroscopy and Analytical Data Modelling)	
24	Terms of reference	
25	 Drafting and revision of general chapters allocated to the group by the Commission in the field of: 	
26 27	 Chemometrics, i.e. modelling of analytical data (e.g. Multivariate Data analysis, Data mini Chemical imaging etc.) 	ng,
28 29	 measurement techniques relying extensively on analytical data modelling (NIR, RAMAN) other vibrational spectroscopies (IR) 	or
30 31	 provide support to the PAT WP where PAT/ QbD elements of the above mentioned chapt are concerned 	ers
32	Profile for experts	
33 34	 Current expertise vibrational spectroscopy related to quality control of active substances and excipie and in development of control methods 	nts
35	 Several years of experience in one or more of the following fields: 	
36 37	 Use of near infrared spectrometry and other vibrational spectroscopic techniques for qual control in a pharmaceutical manufacturing setting 	ity
38 39 40	 Development of pharmaceutical control methods using near infrared spectrometry and other vibrational spectroscopic techniques or chemometrics in a research and development environment 	
41	 Assessment of applications for marketing authorisation 	
42	 Market surveillance of quality in of texts 	
43	 Pharmaceutical quality control in an independent testing laboratory 	
4.4	W.I.M.W. I.I. B. G.	

44 WAT Working Party (Water)

45 Terms of reference

1	•	Drafting and revision of monographs and general chapters allocated to the group by the Commission in
2		the field of water
3	•	International harmonisation of monographs and general chapters as decided by the Commission
4	Profile.	for experts
5	•	Current expertise in analytical methods applicable in water analysis in development of control methods
6	•	Several years of experience in one or more of the following fields:
7		 Quality control of water in a pharmaceutical manufacturing setting
8		 Inspection of manufacturing sites
9		 Pharmaceutical quality control in an independent testing laboratory
10		 Development of methods for control of pharmaceutical waters in a research and development
11		environment
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