Expert field	full title	Responsible department	characteristics of the working group	Web contact
		EMEA		
MB	Management Board	MEZ	The Management Board is an integral governance body of the European Medicines Agency (EMEA). The Board has a supervisory role with general responsibility for budgetary and planning matters, the appointment of the Executive Director and the monitoring of the Agency's performance.The Board's operational tasks are very broad, ranging from adopting legally binding implementing rules, to setting strategic directions for scientific networks, to reporting on the use of Community contributions for a range of activities.	http://www.emea.europa.eu/htms/general/manage/MB/MB_overview.html
CHMP	Committee for Human Medicinal Products	REG-PPK	The Committee for Medicinal Products for Human Use (CHMP) is responsible for preparing the Agency's opinions on all questions concerning medicinal products for human use, in accordance with Regulation (EC) No 726/2004.In the 'Community' or 'centralised' procedure, the CHMP is responsible for conducting the initial assessment of medicinal products for which a Community-wide marketing authorisation is sought. The CHMP is also responsible for several post-authorisation and maintenance activities, including the assessment of any modifications or extensions ('variations') to the existing marketing authorisation.	http://www.emea.europa.eu/htms/general/contacts/CHMP/CHMP.html
		CHMP Working Parties		
BWP	Biologics Working Party	REG-PF	The Biologics Working Party (BWP) was established to provide recommendations to the EMEA scientific committees on all matters relating directly or indirectly to quality and safety aspects relating to biological and biotechnological medicinal products.	http://www.emea.europa.eu/htms/general/contacts/CHMP/CHMP_BWP.html
EWP	Efficacy Working Party	REG-PPK	The Efficacy Working Party (EWP) provides recommendations to the CHMP on all matters relating directly or indirectly to the clinical part of drug development.	http://www.emea.europa.eu/htms/general/contacts/CHMP/CHMP_EWP.html
QWP	Joint CHMP/CVMP Quality Working Party	REG-PF,LAB	The Joint CHMP/CVMP Quality Working Party (QWP) provides recommendations to the Committees on matters relating directly or indirectly to the quality of human or veterinary medicinal products. On request of the Committees, the QWP is involved in such areas as the preparation, review and update of quality guidelines, the provision of scientific advice on general and product-specific matters relating to quality, the resolution of national divergences regarding the assessment of quality issues, liaison with interested parties, international cooperation on quality-related matters, etc.	http://www.emea.europa.eu/htms/general/contacts/CHMP/CHMP_QWP.html

PhVWP	Pharmacovigilangce Working Party	KHF-PhV	The mission of the Pharmacovigilance Working Party is to provide recommendations to the CHMP on all matters relating directly or indirectly to 'pharmacovigilance' - the constant monitoring of medicinal products on the market. This involves providing advice on the safety of medicinal products and on the investigation of adverse reactions associated with medicinal products authorised in the EU, enabling the CHMP to effectively identify, assess and manage risk at any phase in the lifecycle of a medicinal product.	http://www.emea.europa.eu/htms/general/contacts/CHMP/CHMP_PhVWP.html
SWP	Safety Working Party	REG-PPK	The Safety Working Party (SWP) provides recommendations to the CHMP on all matters relating directly or indirectly to non-clinical aspects of safety.	http://www.emea.europa.eu/htms/general/contacts/CHMP/CHMP_SWP.html
SAWP	Scientific Advice Working Party	REG-PPK	The SAWP is a permanent working party of the CHMP, in charge of Scientific Advice and Protocol Assistance for orphan medicinal products.	http://www.emea.europa.eu/htms/general/contacts/CHMP/CHMP_SAWP.html
Other CHMP associated Groups				
NRG	Name Review Group	REG-ORA	The group is obliged to consider whether the invented name proposed for a medicinal product by its manufacturer could create a public-health concern or potential safety risk.	http://www.emea.europa.eu/htms/general/contacts/CHMP/CHMP_INRG.html
QRD	Working Group of Quality Review of Documents	REG-KOR	The Working Group on Quality Review of Documents (QRD) provides assistance to the EMEA scientific committees and to companies on linguistic aspects of the product information (summary of product characteristics, labelling and package leaflet) for medicines.	http://www.emea.europa.eu/htms/general/contacts/CHMP/CHMP_QRD.html
COMP	Committee for Orphan Medicinal Products	REG-PPK	The Committee for Orphan Medicinal Products (COMP) is responsible for reviewing applications from persons or companies seeking 'orphan medicinal product designation' for products they intend to develop for the diagnosis, prevention or treatment of life-threatening or very serious conditions that affect not more than 5 in 10,000 persons in the European Union.	http://www.emea.europa.eu/htms/general/contacts/COMP/COMP.html
HMPC	Committee on herbal Medicinal Products	REG-PF	The HMPC's activities aim at assisting the harmonisation of procedures and provisions concerning herbal medicinal products laid down in EU Member States, and further integrating herbal medicinal products in the European regulatory framework.	http://www.emea.europa.eu/htms/general/contacts/HMPC/HMPC.html
HMPC working parties				
MLWP	Working Party on Community Monographs and Community list	REG-PF	The MLWP's core task is to carry out assessment work in relation to the establishment of Community herbal monographs and entries to the 'Community list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products'.	http://www.emea.europa.eu/htms/general/contacts/HMPC/HMPC_MLWP.html

PDCO	Paediatric Committee	REG-PPK	The main responsibility of the Paediatric Committee (PDCO) is to assess the content of paediatric investigation plans and adopt opinions on them in accordance with Regulation (EC) 1901/2006 as amended. This includes the assessment of applications for a full or partial waiver and assessment of applications for deferrals.	http://www.emea.europa.eu/htms/general/contacts/PDCO/PDCO.html
CAT	Committee for Advanced Therapies	REG-PPK	The main responsibility of the CAT is to prepare a draft opinion on each ATMP application submitted to the EMEA, before the Committee for Medicinal Products for Human Use (CHMP) adopts a final opinion on the granting, variation, suspension or revocation of a marketing authorisation for the medicine concerned.	http://www.emea.europa.eu/htms/general/contacts/CAT/CAT.html
CMD(h)	Co-ordination Group for Mutual Recognition and Decentralised Procedures - Human	PRO/REG-PPK	CMDh assesses all questions related to marketing authorisations in two or more Member States in compliance with mutual recognition and decentralised procedure.	http://www.emea.europa.eu/cmdh.htm
EV-EWG	Eudravigilance Expert Working Group	KHF	The main task of the group are all aspects related to the practical implementation, operation of and access to EudraVigilance in the pre- and post-authorisation phase in line with the requirements as defined in Community legislation.	http://eudravigilance.emea.europa.eu/human/evEWGroup.asp
PIM	Product Information Management	REG-PF, PPK	PIM is a standard for the electronic exchange of product information in the context of marketing authorisation applications. It describes how the required information should be created and validated so that it can be exchanged successfully between applicants and competent authorities. The design of the standard aims to minimise the repeated adjustment of information that is included many times in different locations within the documents provided in support of current processes.	http://pim.emea.europa.eu/
TIGes				
eCTD	eCTD Implementation Group - TIGes/NtA	ADM	Working group dealing with the implementation of electronic marketing authorisation submissions project.	
EudraPHARM database	EudraPHARM database	INF	EudraPharm is a database containing information on medicinal products for human and veterinary use registered within the EU.	http://euteleproj.eudra.org/eudrapharm/library.htm
EudraNet TIG	EudraNet	INF	The working group deals with the data connection related isssues among medicines agencies.	
EV TIG	Eudravigilance TIG	KHF	The meeting of NCA representativies deals with the operation and use of EudraVigilance system within EEA. EV TIG deals with functioning EV database - software update, Access Policy, personal data protection, business rules etc. The members are informed on particular IT projects, their impact and how to access them.	
EudraCT	EudraCT + EudraCt Task Force- Joint Operations Group, Eudra CT TIG	KHF	EudraCT is a database of all clinical trials, that were started after 1 May, 2004.	https://eudract.emea.europa.eu/
PMF IS	Expert concerning Plasma Master Files	REG-PF	The PMF is a compilation of all the required scientific data on the quality and safety of human plasma relevant to the medicines, medical devices and investigational products that use human plasma in their manufacture. These data cover all aspects of the use of plasma, from collection to plasma pool.	http://pim.emea.europa.eu/

EUTCT	EU Telematics Controlled Terms	INF	EUTCT is a Community repository and provider of controlled terms in multiple languages for the ongoing exchange of data between information systems and applications throughout the European Medcines Regulatory Network.	http://eutct.eudra.org/eutct/
EMEA ad hoc skupiny				
GMP IS	Ad hoc meeting of GMP	INS	The GMP working group deals with the impact of legislature on GMP inspections and GMP inspections harmonisation.	
GCP IS	Ad hoc meeting of GCP	INS	GCP is a working group aiming at harmonisation and coordination of activities related to GCP within EU.	
GCP IWG	GCP Inspectors Working Group	INS	The GCP Inspectors Working Group focuses on harmonisation and co-ordination of GCP related activities at Community level.It is involved in the preparation of new and revised guidance on GCP and community procedures relating to inspection.	http://www.emea.europa.eu/Inspections/GCPInspmtg.html
HMA				
HMA	Heads of Medicines Agencies		The Heads of Medicines Agencies from Member States of the European Union and the European Economic Area competent in the field of regulation of human and veterinary medicinal products deal with the strategic, technical and organisational aspects related to safety, efficiency and quality of human and veterinary medicinal products in Europe. The meeting aims also at harmonisation of activities improving the effectiveness of the network of the Medicines Agencies. The exact programme will be tailored to the actual situation in the area of pharmaceuticals and the topics submitted within the frame of the working groups to Heads of Medicines Agencies.	http://www.hma.eu/
HMPWG	Homeopathic Medicinal Products Working Party	REG-PF	The Committee creates a forum for exchange of scientific and regulatory experience regarding the assessment of the quality and safety of homeopathic medicines in the EU Member States and the European Economic Area. Another important function of the Committee is harmonisation, scientific expertise and general facilitation of the process of homeopathic medicinal products registration.	http://www.hma.eu/79.html
EMACOLEX	Legal co-operation of the European Medicines Agencies	PRO	Legal co-operation of the European Medicines Agencies envisages grouping of the legal experts of the EU and EEA Member States' medicines agencies. The main purpose of the informal meeting is to strengthen and facilitate dialogue and mutual collaboration between individual Member States in respect of interpretation and analysis of EU legislature in the area of medicinal products, EJC case-law and topical issues concerning the pharmaceuticals market.	
HMA WGEO	Working group of enforcement officers	EDR	The meeting of inspectors of Medicines Agencies and representatives of Competent Authorities from EU and EEA states aims at ensuring adherence to the regulations governing pharmaceuticals manufacturing and distribution chains. It also follows the objective to define strategies and procedures for combating counterfeit medicinal products. The WGEO contributes to the protection of public and animal health. The meeting of the group allows its members to share information on illegal activities and violation or potential violation of legal manufacturing and distribution chains in the area of both human and veterinary medicinal products.	

HMA WGQM	Working Group of Quality Managers	QM	The Working Group assembles the quality managers from all the Medicines Agencies of the EU and EEA Member States, representatives of the European Medicines Agency and the European Commission. Its goal is to provide guidance in the area of quality management and best practise benchmarking, and to design and facilitate the implementation thereof in order to increase the efficiency of processes within the Medicines Agencies.	
HMA WGCP	Working Group of communication professionals	TIO	The Working Group's aim is to create a unified communication strategy of the EU Member States' Medicines Agencies. In particular, it deals with the issue of provision of information to the general and professional public. The current task is to identify a group of key partners (stakeholders) and set rules for communication with them.	
CTFG	Clinical Trials Facilitation Group	KHF	In relation to clincial trials the CTFG acts as forum for discussion to agree on common principles and processes to be applied throughout the European medicines regulatory network (EMRN). It also promotes harmonisation of clinical trial assessment decisions and administrative processes across the national competent authorities (NCA).	http://www.hma.eu/78.html
European Commission				
SC for human medicinal products	Standing Committee for human medicinal products	PRO	Standing Committee approves legislature and provisions related to running medicines agencies within EU.	
PC	Pharmaceutical Committee		The Pharmaceutical Committee is an advisory Committee with the task of examining all questions relating to proprietary medicinal products and, in particular, the preparation of proposals for Directives.	http://ec.europa.eu/enterprise/pharmaceuticals/committees/pharm-com_en.htm
TC	Transparency committee	CAU	The Committee is to inform the members on the current situation related to implementation of the Transparency Directive.	
MDEG- Vigilance	Medical Device Expert Group on Vigilance	NPP	MDEG is a forum to discuss all issues relating to the implementation of the medical device directives with Member State Competent Authorities.	http://ec.europa.eu/enterprise/medical_devices/working_group.htm
Council of the European Union	Working Party on Pharmaceuticals and Medical Devices	PRO	The working group assesses legal proposals.	
Council of the European Union				
EDQM - European Directorate for Quality of medicines and healthcare	Group of experts 15, European Pharmacopea- sera and vaccines	LAB	Working group specializing in creation and correction of pharmacopeia articles and clauses in the field of vaccines.	http://www.edqm.eu/en/Homepage-628.html
EDQM - EPC	European Pharmacopoeia Commission	LAB	The European Pharmacopoeia Commission has set the goals of rapidly increasing the number of European monographs (more than 2000 available so far), reducing the time needed to elaborate them, and, if the need is expressed, elaborating monographs on recent substances still under patent protection.	http://www.edqm.eu/en/Work-ProgrammeStatus-607.html

CD-P-PH	Evr. Výbor pro farmaceutika a farm. Péči	LAB	The group contributes to improving public health care through harmonising provisions and practices involving pharmaceuticals in Europe and minimises public health risks posed by counterfeit medicines and other forms of pharmaceutical crimes through multisectorial prevention and risk management strategies and the support to the elaboration and implementation of relevant national legislation and international legal instruments.	http://www.edqm.eu/site/CD-P-PH-The-European-Committee-on-Pharmaceuticals-and-Pharmaceutical-Care-1327.html
RE-EDQM-OMCL	Official Medicines Control Laboratories Network	LAB	OMCLs are official laboratories who support regulatory authorities and complement the inspection services in controlling the quality of medicinal products on the market by independent testing. It is an independent laboratory responsible for the quality control of medicines for human and veterinary use.	http://www.edqm.eu/en/Quality-Assurance-Activities-19.html
RE-EDQM-OCABR	Official Medicines Control Laboratories (OMCL)-Advisory Group	LAB	It is an important forum for confidential exchange of quality and technical information on products and methods and a key link in the regulatory chain for biological medicinal products.	http://www.edqm.eu/en/Human-Biologicals-OCABR-611.html
RE-EDQM-CAP	Centrally Authorised Product - Advisory group	LAB	The programme is aimed to check compliance with both current Good Manufacturing Practices (GMP)* and the Certificate of Suitability (CEP) application dossier (and any updates) at the manufacturing/distribution sites covered by CEPs.	
RE-EDQM-GEON	Advisory Group GEON (OMCL)	LAB	Advisory group of OMCL advisory network dealing with creation of documents.	
EDQM-OMCL-MRP/DCP	MRP/DCP meeting - MRP administrator	LAB	The goal is to coordinate laboratory activities related to MRP/DCP products and the exchange of experience with methods used for analysis by risk based sampling.	
RE-AHG on CM	Ad Hoc group on Counterfeit Medicines	EDR	the Council of Europe *Ad hoc* Group on Counterfeit Medicines developed a model for a network and SPOCs and adopted it in June 2007. This model establishes a network of entities responsible for the management of notifications of medical products suspect of being counterfeit or of other pharmaceutical crimes.	http://www.edqm.eu/site/Counterfeit-medicines-SPOCs-1178.html?PHPSESSID=ccba42071b4678034335c85feec3c6ff
CD-P-PH/CMED	Com. Of experts on minimising public health risks posed by counterfeiting of medicinal products	EDR	The Committee CD-P-PH/CMED was entrusted with a comprehensive work programme focusing on public health protection from counterfeiting of medicines and related crimes through risk management and prevention, and improved co-operation of member states and other stakeholders in Europe and beyond.	http://www.edqm.eu/en/Counterfeit-medicines-1189.html
CD-P-PH/PHO	Committee of Experts on the classification of medicines as regards their supply	REG	The Council of Europe is concerned since long with the supply conditions of medicines for human use and the harmonisation of national legal provisions in this field.The legal classification of medicines has implications on patient safety, the accessibility of medicines and the responsible management of health care expenditure. There is a growing trend to make medicines available as OTC medicines.	http://www.edqm.eu/site/CD-P-PHO-Committee-of-Experts-on-the-classification-of-medicines-as-regard-their-supply-CD-P-PHPC-1328.html

CD-P-PH/PC	quality and safety standards i pharmaceutical practices and pharmaceutical care	PRO	the Committee CD-P-PH/PC was entrusted with a programme aimed at improving pharmaceutical care and practices in community, ambulatory and hospital care through specific programmes and policies, putting first the needs of patients and society in general, valuing the social and ethical context of healthcare.Current priorities of the Committee CD-P-PH/PC comprise the development of provisions and practices in the field of • quality assessment in pharmaceutical practice and care in Europe through quality indicators, • new roles of the pharmacist in Europe inter alia raising medication-related health literacy of the public.	http://www.edqm.eu/en/CD-P-PC-Committee-of-Experts-on-quality-and-safety-standards-in-pharmaceutical-practices-CD-P-PHPC-1329.html
OECD				
GLP WG	GLP working group	INS	Working group dealing with the issues related to good laboratory practice.	http://www.oecd.org/document/56/0,3343,en_2649_34381_1935800_1_1_1_1,00.html
PIC/S	Pharmaceutical Inspection Cooperation Scheme Committee of Representatives	INS	It is a group of GMP inspectors. It works in compliance with the Pharmaceutical Inspection convention. The main responsibilities comprise the creation of network and confidence among particular inspection authorities, creation of quality systems, training of inspectors and other experts and all activities leading to global harmonisation of GMP.	http://www.picscheme.org/pics.php
PIC/S State Pharmaceutical Inspection	Expert Circle on Hospital Pharmacy	LEK		http://www.picscheme.org/role.php
WHO				
EANM	European Association of Nuclear Medicine	LAB	EANM spreads information in the field of nuclear medicine and related issues.	https://www.eanm.org/
ISDB	International Society of Drug Bulletins, General Assemly 2005	PIR	The International Society of Drug Bulletins (ISDB) is a world wide network of bulletins and journals on drugs and therapeutics that are financially and intellectually independent of pharmaceutical industry. The overall aim of ISDB is to encourage and assist the development of independent drug bulletins in all countries and to facilitate co-operation amongst them.	http://www.isdbweb.org/pag/publications.php