WORKING GROUPS AND STUDY GROUPS
of Pharma Deutschland e.V.

Status 23. September 2025

In addition to working on a committee, there is also the opportunity to get involved in one of Pharma Deutschland's numerous working groups **(WGs)**, sub-working groups **(S-WGs)** and study groups **(SGs)**. In this case, there is no appointment needed by the Executive Board, you can just contact the named contact person / assistant of the relevant group directly and informally.

There are working groups **(WGs)** on all areas of our association. A list of the working groups **(WGs),** sub-working groups **(S-WGs)** and study groups **(SGs)** is attached, arranged according to subject area.

Please note that all sessions will be held in German.

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1. Electronic Submission

1.1 WG Electronic Submission

Since 2005, there has been a cross-authority and cross-association working group for the area of electronic submission, consisting of representatives from many member companies of Pharma Deutschland and the BPI & vfa, as well as representatives from the three regulatory authorities BfArM, PEI and BVL. The task of the working group is to develop and monitor procedures supporting the exchange of data between authorities and industry in electronic form, both in Germany, at European and international level. The working group meets three to four times a year and is supported in its work by some independent sub-working groups, currently five, on the dedicated topics of IDMP, eAF, ePI, eCTD and AI.

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1.2 WG IDMP Substance WG3 Mirror

This working group is a mirror group for the work on the European substance database EU-SRS. The focus is on the correct and complete representation of herbal and homeopathic medicinal products in the substance database.

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1.3 S-WG IDMP Germany

This sub-working group deals with the European projects for the implementation of the ISO IDMP standards for the coding of pharmaceuticals. It primarily supports the various EMA projects in this sector.

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1.4 S-WG ePI Germany (see also 3.4)

This inter-association (Pharma Deutschland, BPI, VfA) sub-working group supports the German and European projects for the creation, storage and maintenance of electronic product information.

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1.5 S-WG eAF

This sub-working group deals with the introduction and maintenance of electronic application forms at European level.

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1.6 S-WG eCTD

The sub-working group supports the implementation of the electronic application dossier in the international eCTD (ICH topic M8) format in Europe. It is also pursuing the introduction and use of electronic application dossiers in other European countries and worldwide.

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1.7 S-WG KI

The sub-working group supports the application of concepts and solutions based on artificial intelligence in the lifecycle of pharmaceuticals and medical devices. It follows the work of the relevant working groups regarding ISO and DIN and monitors legal developments at German and European level.

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2. Environment and Chemicals

2.1 WG Acrylates (currently inactive – will be reactivated if required)

The Acrylates Working Group was established because proposals for the harmonised classification and labelling (CLH) of Hydroxyethyl Methacrylate (HEMA) and Methacrylic Acid (HPMA) were submitted. Currently, the working group is inactive but can be reactivated if needed.

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2.2 WG BPA (currently inactive – will be reactivated if required)

In the Bisphenol Working Group, bisphenols and their derivatives are discussed. Bisphenols are used in the production of polymers and resins, which are ultimately used to manufacture plastic materials, including those used in the dental industry. Bisphenols constitute a large group with many substances having similar chemical structures, the most well-known being Bisphenol A (BPA).

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2.3 WG Ethanol

This working group was established in connection with the approval process of ethanol as a biocidal active substance according to the Biocidal Products Regulation (EU) No. 528/2012 and the subsequent CLH procedure for harmonised classification under the CLP Regulation (No. 1272/2008), to keep member companies up to date and coordinate joint activities. The aim of this "Ethanol" working group is to develop a common position and propose solutions. Additionally, Pharma Deutschland aims to provide its member companies with a platform for regular exchange.

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2.4 WG “OSOA”

On 7 December 2023, European Commission presented a reform package for the “One substance, one assessment” initiative. The ‘one substance one assessment’ package contains three proposals: one directive concerning the re-attribution of scientific and technical tasks, one regulation aimed at enhancing cooperation among Union agencies in the area of chemicals and one regulation establishing a common data platform on chemicals.At the request of some member companies, the working group was established to closely monitor and comment on the legislative process.

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2.5 WG PFAS

On 13 January 2023, the national authorities of Denmark, Germany, the Netherlands, Norway and Sweden submitted a proposal to the ECHA to restrict per- and polyfluoroalkyl substances (PFAS) under REACH, the European Union’s (EU) chemicals regulation. To analyse this extensive restriction proposal, develop a joint commentary, and monitor the process, the "PFAS" working group was established.

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2.6 WG Substance Information from CLP and REACH

To support its members in answering the diverse questions regarding REACH and CLP, Pharma Deutschland is establishing the working group "Substance Information from CLP and REACH."

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3. Europe and International Affairs

3.1 WG Eurasian Economic Union (EAEU)

The Eurasian Economic Union is an association of five states (Russia, Kazakhstan, Belarus, Armenia, Kyrgyzstan) in north-eastern Eurasia established to create a single market with a customs union. The EAEU aims to facilitate the free movement of goods, capital, services and labour. In this context, a common market for pharmaceuticals was launched in May 2017. The legal acts governing the quality, manufacture, and classification of pharmaceuticals are aligned with international standards and closely modelled on the relevant legislation of the European Union.

The EAWU WG of Pharma Deutschland provides a platform for the exchange of information and expertise. Furthermore, Pharma Deutschland can contribute to political process based on the results of the working group's findings, thereby representing the interests of its member companies.

The EAWU WG meets online two to three times a year. Invitations are issued via our newsletter "Pharma Deutschland aktuell".

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3.2 WG China

China is the global leader in the manufacture and export of active pharmaceutical ingredients (APIs). At the same time, China relies heavily on imports for finished pharmaceuticals, with Germany playing a key role. German pharmaceuticals and medical devices enjoy an excellent reputation in China. However, the Chinese government is increasingly pursuing a strategy to reduce dependence on foreign products, reflected in its "Buy China" policy and the and the push for greater localisation.

The China WG provides a platform for the exchange of information and expertise on current challenges in the Chinese market. Topics include new regulatory requirements for licencing, quality assurance and production, political and legal framework conditions, market access, and distribution strategies.

The China WG meets online two to three times a year. Invitations are issued via our newsletter "Pharma Deutschland aktuell".

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4. Healthcare

4.1 Healthcare HUB

The healthcare hub addresses overarching topics that may be relevant to the supply of medicines in the future. The members are dedicated to various issues related to healthcare, e.g. cross-sectoral care, trends towards outpatient instead of inpatient treatment and innovative forms of care. The focus is on relevant legal and practical developments as well as the impact on the pharmaceutical market and reimbursement. External speakers, for example from the medical profession or health insurance companies, regularly provide impetus. The HUB usually meets online three times a year.

The HUB is led by Mrs Steffi Liebig, APOGEPHA Arzneimittel GmbH.

Owing to its central supply role, the HUB is assigned to the committees of the Innovative Healthcare Department (German: IGV), and in particular the Market and Reimbursement Committee.

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4.2 WG Vaccines

Vaccinations are among the most important, efficacious and cost-effective preventive measures available to medicine to protect against infectious diseases. However, vaccination rates in Germany are worryingly low by international standards and are stagnating. Furthermore, lengthy negotiation processes for vaccination agreements prevent easy and rapid access to certain vaccinations. Similar to pharmaceutical production and research, the expansion and promotion of existing capacities as well as research into new vaccines must be focused and implemented to ensure local and safe supply in Germany and Europe.

Against this background, the Vaccines working group deals with all vaccine-related topics across all departments, including:

- Measures to increase the vaccination rate, particularly with a focus on low-threshold access
- Framework conditions for the reimbursement of vaccinations
- Production and local supply of vaccines
- Regulatory affairs and licensing as well as research into new vaccines

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4.3 WG Digital Health Applications

With the introduction of digital health applications (German: DiGA) as a new service area in 2019, the DiGA market is in a constant state of flux and continually faced with new requirements. The DiGA working group offers member companies a platform for knowledge-sharing on licensing issues within

the framework of the fast-track procedure, reimbursement issues, topics relating to implementation in healthcare and the future direction of the service area.

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5. Herbal medicinal Products

5.1 WG Extracts

The Pharma Deutschland extract manufacturers working group deals with the scientific processing of fundamental questions regarding the quality assurance of drugs and herbal extracts. Manufacturers producing extracts or respective herbal starting materials in scope of the pharmaceutical legislation are represented on this committee.

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5.2 WG Contaminants

This working group jointly maintains databases with analysis data on herbal raw materials (e.g. pesticides, heavy metals), discusses current developments in the production of herbal active ingredients and jointly prepares publications from the database analyses.

The participating companies finance the projects jointly and proportionately.

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5.3 WG PA Database

The cross-association Pharma Deutschland/BPI working group deals with the collection of analytical data on pyrrolizidine alkaloids (PA) in herbal material to provide lines of reasoning with the authorities; the working group also follows current developments and has drawn up and implemented a “Code of Practice”.

The participating companies finance the projects jointly and proportionately.

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5.4 WG Phyto GMP (currently inactive)

Herbal medicinal products and active ingredients are generally subject to the same manufacturing requirements in accordance with Good Manufacturing Practice (GMP) as other pharmaceuticals. This working group therefore discusses all relevant issues relating to GMP in the manufacture of

herbal active ingredients and medicinal products and produces publications on individual topics. For example

- Differentiation GACP/GMP
- Questions about ongoing stability checks
- Purification validation for products of plant origin.

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5.5 WG Stability

The stability working group deals with regulatory issues relating to the stability of herbal medicinal products. Herbal medicinal products are complex mixtures of multiple substances, and analysing and assessing their stability poses a number of challenges. The working group discusses open questions, e.g. on the assessment of marker substances or fingerprint chromatograms and publishes scientific papers on the subject.

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6. Homeopathic and anthroposophic medicines

6.1 WG Homeopathic and Anthroposophic Medicines (HAAM)

The working group deals with regulatory issues relating to homeopathic and anthroposophic medicinal products, in particular their quality, efficacy and safety. The working group also promotes specialist knowledge-sharing between the companies on current information from European authorities.

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6.2 WG Viral Safety

The Pharma Deutschland/BPI interdisciplinary working group deals with regulatory issues relating to the viral safety and harmlessness of homeopathic and anthroposophic medicinal products based on animal source materials. The working group prepares dossiers and recommendations for action for the companies, which can be used for regulatory purposes.

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7. Legal Affairs

7.1 WG Revision of Pharmaceutical Legislation

This cross-committee and interdisciplinary working group analyses and identifies whether and which proposals can be made as part of the pharmaceutical strategy at EU level with regard to a revision of pharmaceutical legislation. It also prepares opinion statements for consultation procedures on draft regulations etc. as required as part of the strategy.

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8. Medical Devices

8.1 WG Aesthetic Medicine (currently inactive)

This group focuses on the special concerns of aesthetic medicine products which are not covered by the other working groups of the association. These are primarily products that are subject to medical device legislation. The working group provides an information and discussion platform for companies operating in this sector.

The working group meets on an ad hoc basis as required.

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8.2 WG Dental

As a rule, manufacturers of dental medical devices do not have any medicinal products in their portfolio. The Dental working group was set up for these manufacturers for this reason and has a separate membership fee schedule. Representatives of these manufacturers meet at least three times a year to discuss regulatory matters for these special medical devices. The Dental working group focuses particularly on regulatory issues and their implementation in practice.

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8.3 WG Exchange on Experience: Drug-Device Combinations (see also 3.1)

Medicinal products and medical devices that are placed on the market as a combined product are generally referred to as “Drug-Device Combinations”. As there have been changes to the required documentation for these products following the entry into force of MDR and IVDR (Regulation (EU) 2017/745 and 2017/746), the working group was set up to offer our member companies a forum for

exchange of experience and to discuss issues related to the implementation of the above-mentioned regulations.

The working group meets on average every two months.

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8.4 WG EUDAMED-Exchange of experience

The European Medical Devices Database (EUDAMED) is to be introduced gradually and the first modules are expected to be mandatory by the end of 2025. Three of six EUDAMED modules are currently available. These are the modules “Actor Registration”, “UDI/Device” and “NBs & Certificates”. Two further modules, “Vigilance” and “Market Surveillance”, should be available shortly. The finalisation of the “CI/PS” module has been delayed. In order to support its members in implementing the new requirements, Pharma Deutschland e.V. has founded the “EUDAMED-Exchange of experience” working group. Participants share their experiences with the various EUDAMED modules.

The working group meets as required.

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8.5 WG Clinical Evaluation of Medical Devices

The working group discusses general issues relating to clinical evaluation with a particular focus currently on the implementation of the MDR requirements (Regulation (EU) 2017/745 on medical devices). Assistance is also provided for member companies of Pharma Deutschland by providing explanations and for understanding the content of the legislation as well as the practical implementation of the regulatory content. Another focus is on supporting the development of legal texts at both German and European level.

The working group meets three times a year.

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8.6 WG Clinical Trials of Pharmaceuticals and Medical Devices (see also 6.1)

In the field of clinical research, Pharma Deutschland e.V. currently has a combined working group on the topic of “Clinical Trials”, which deals with general issues relating to clinical research with both areas, pharmaceuticals and medical devices. in Germany. The working group supports on a broad basis the development of legal texts at both German and European level; currently it has a particular focus on the implementation of the European regulations (MDR, Medical Device Regulation and CTR, Clinical Trials Regulation) in both fields. The working group also provides assistance to Pharma Deutschland member companies in explaining and understanding the content of the law and in implementing the regulations in practice.

The working group meets three times a year.

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8.7 WG Medical Gases (currently inactive)

The special concerns of medical gas manufacturers are discussed in the working group. In the past, these related to the application and interpretation of legal regulations for medical gases, primarily in the fields of manufacturing (GMP) and Good Distribution Practice (GDP).

This working group meets as required.

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8.8 WG OEM-PLM (finished product supplier) (currently inactive)

The Original Equipment Manufacturer-Private Label Manufacturer (OEM-PLM) cooperation is a special form of subcontracting/supplier relationship and thus an existing and secure concept in the medical device sector. This OEM-PLM concept was possible under the MDD (Medical Device Directive) and is possible under MDR (Medical Device Regulation). Under the MDR, however, there are stricter obligations for the PLM to personally ensure that the medical device placed on the market under its name conforms with the legal requirements. Therefore, the PLM must have a certain degree of control over the OEM's complete technical documentation and production to ensure that compliance is guaranteed.

This working group develops assistance for the member companies concerned regarding the proper handling of this cooperation in accordance with the MDR, e.g. in the form of position papers or templates.

The working group meets as required.

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8.9 WG Implementation of the MDR for Dental Products (currently inactive)

This working group is aimed exclusively at member companies with dental medical devices that occupy a certain special position (e.g. many of these products are categorised as implants). While the Dental working group focuses more on regulatory/legislative issues, the work of this group is centred more on the practical implementation of requirements and the drafting of statements.

This working group meets as required.

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8.10 WG Vigilance for Medical Devices

Regulation (EU) 2017/745 on medical devices (MDR – Medical Device Regulation) places many increased and new requirements on manufacturers of medical devices, particularly regarding vigilance. For example, the reporting period for "serious incidents" has been shortened from 30 days to 15 days (Article 87(2) MDR). As a result, since May 2021, manufacturers have had to apply new guidance documents and use many new vigilance templates. In addition to commenting on these documents and their drafts, this working group discusses in particular solution strategies for implementing the new requirements.

The working group meets three to four times a year.

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8.11 SG SOPs for Medical Devices

The implementation of regulatory issues in operational practice is also laid out in the corresponding Standard Operating Procedures (SOPs), which are drawn up by the members of the SOPs for Medical Devices study group and which can provide suggestions and assistance for a company's own SOPs.

A number of regulatory requirements differ, particularly in the details, depending on whether they refer to medicinal products or medical devices, e.g. regarding pharmacovigilance and medical device vigilance. As a result, in-house company procedures for these areas can generally no longer be described in a joint SOP.

This study group has produced two manuals with a total of 16 SOPs and several work instructions. These SOPs are currently being adapted to the requirements of Regulation (EU) 2017/745 on medical devices (MDR – Medical Device Regulation).

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9. Pharmaceutical Development

9.1 WG Nitrosamines

This working group was established at the request of the member companies in order to discuss current developments in connection with nitrosamine contamination and to facilitate knowledge sharing between the member companies concerned. On the other hand, the implementation of regulatory requirements will be discussed in greater depth and as specifically as possible.

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10. Pharmaceutical Technology / GMP

10.1 WG Annex 1

This temporary working group was set up to provide assistance in implementing requirements of the new Annex 1. Additionally, the working group aims to offer a platform for member companies to exchange information regarding the implementation.

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10.2 WG Drug Precursors for Formulation (currently inactive)

At the interfaces between AMG, AMWHV, pharmacy operating regulations, GMP on the one hand and chemicals trade and hazardous substances legislation on the other, questions of interpretation repeatedly arise which have different consequences for the classification of activities and products as well as for the placing of formulation starting materials on the market. The aim of the working group is to form opinions and develop positions in order to take account of legal changes and official interpretations/requirements.

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10.3 WG Ongoing Process Verification (currently inactive)

This working group is a temporary working group that is developing an SOP for “Ongoing Process Verification during Lifecycle”. The finalised manuscript will be published in PharmInd.

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10.4 WG Standards for the Transport of Pharmaceuticals (currently inactive)

The working group has drawn up a position paper with the aim of establishing standards for the aspects of transport temperature range, quality management (at the transport service provider) and deviation management (at the transport service provider), taking into account good distribution practice (GDP). This will ensure the quality of the products and also takes the conditions in the supply chain into account.
In addition, the working group has drawn up a paper setting out the obligations of the contractor and the client with an allocation of responsibilities.

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10.5 WG Titanium dioxide and other Excipients

This working group was established to serve as a mirror committee for the activities of the European manufacturers' associations, particularly in the search for alternatives to titanium dioxide. Additionally, it aims to provide a platform for member companies to exchange information on both galenic and regulatory issues.

In addition to monitoring European developments, international developments concerning titanium dioxide are also being observed.

As there are other excipients that have come into the focus of public discussion, Pharma Deutschland proposed expanding the scope of the working group to include "other excipients". the attendees agreed, and thus the name of the working group is now "Working Group on Titanium dioxide and other Excipients".

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10.6 SG Analytical Validation

This study group is currently working on updating the validation of analytical methods. The reason for this was the revision of ICH Q2 (R2) "Validation of analytical procedures" and the newly implemented ICH Q14 "Analytical procedure development".

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10.7 SG Audit Guideline

The qualification of all suppliers of a pharmaceutical company includes an audit of the relevant manufacturers or suppliers, particularly in the case of active pharmaceutical ingredients. As the audit and in particular the audit reports are not only important for official inspections experts from Pharma Deutschland member companies have developed an audit guideline including an audit report template form in order to optimise them. In addition, the members of the study group have also drawn up audit checklists and self-disclosure questionnaires for various suppliers (distributors of active ingredients and contract inspectors). These questionnaires are used to prioritise audits.

The work of the study groups consists in particular of reviewing the existing SOPs with regard to their need for revision and, if necessary, developing corresponding SOPs for new topics.

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10.8 SG Computer Validation

For computerised systems in the GxP area, Annex 11 of the EU-GMP guidelines has laid down its own requirements.

This study group specifically develops SOPs that implement these special requirements into the operational practice of the company "Example." It has created nearly 20 SOPs, several work instructions, and checklists, which are regularly reviewed for their need for revision. SOPs and other documents on new aspects are developed as needed.

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10.9 SG GDP/GMP for Active Substances/Excipients (currently inactive)

The study group is concerned with the topic of "self-assessment questionnaires." Most recently, the self-assessment questionnaire for "packaging material suppliers" was completed. The existing self-assessment questionnaires are reviewed for the need for revision and, if necessary, updated.

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10.10 SG GMP/GVP Interface (see also 1.1, currently inactive)

This study group deals with SOPs from the GMP sector as well as with SOPs from the pharmacovigilance sector in relation to the GMP/GVP interface and revises them in relation to the interface if necessary.

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10.11 SG Manual Qualification / Validation (currently inactive)

The study group is currently working on updating the Validation Master Plan (VMP), which forms the basis for all qualification and validation activities within the “Sample” company. The SOPs for the qualification of systems and the validation of processes will then be revised.

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10.12 SG HiWi-SOPs (currently inactive)

This study group was founded to support the “SOPs in GMP” study group.

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10.13 SG QM Manual

The QM manual represents the highest of the three hierarchical levels that make up the essential components of a company's QM system. It contains the organisational company know-how and the general quality requirements (in accordance with the EU GMP guidelines), including references to master plans and SOPs.

The study group has created this type of manual for the company "Sample" using the format of the EU GMP guideline (nine main chapters with various sub-chapters).

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10.14 SG SOPs in the GMP Field

This study group consists of two subgroups: "SOPs in the GMP area" and "HiWi SOPs." The auxiliary sciences working group ("HiWi") supports the SOPs working group in the GMP area. Both groups focus on the second hierarchical level of a company's quality management system, namely the standard operating procedures (SOPs). A total of 38 SOPs and several work instructions have been published.
The primary task of this groups is to review the existing SOPs for their need for revision and, if necessary, to develop new SOPs on relevant topics.

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10.15 SG Contracts Manual (currently inactive)

This study group has developed working papers on contract manufacturing, contract testing, supplier evaluation, and quality assurance agreements regarding active ingredients, excipients, pharmaceutical transport, climate control, storage & distribution, and pharmaceutical packaging materials as a type of model contract. They illustrate how the company "Example" implements regulatory requirements in detail.
The primary task of the study group is to review the existing contracts for their need for revision and to develop new contracts on relevant topics.

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11. Pharmaceuticals and the environment

11.1 WG Pharmaceuticals and the Environment (UWWTD)

This new working group will serve as a mirror committee in the pilot phase of the federal government's trace substance strategy and the national water dialogue. It will also deal with the European "Strategic approach to pharmaceuticals in the environment".

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11.2 WG Environmental Risk Assessments (ERA) Knowledge-Sharing

With the revision of EU pharmaceutical legislation through Directive 2004/27/EC, the requirement for an environmental risk assessment (ERA) of medicinal products for human use was enshrined in law. The associated Guideline on the environmental risk assessment of medicinal products for human use of the European Medicines Agency (EMA) was published in revised form in March 2024 and has been applicable since 1 September 2024.

The aim of this working group is to support the implementation of the requirements of the new ERA guideline and serve as a forum for exchange between member companies.

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12. Pharmacovigilance

12.1 WG GMP/GVP interface

This working group deals with SOPs from the GMP sector as well as with SOPs from the pharmacovigilance sector in relation to the GMP/GVP interface and revises them in relation to the interface if necessary.

The working group has developed the SOP: "Implementation of recalls of medicinal products at distribution level and informing the public".

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13. Regulatory affairs

13.1 WG Exchange on Experience: Drug-Device Combinations (see also 9.3.)

Medicinal products and medical devices that are placed on the market as a combined product are generally referred to as “Drug-Device Combinations”. As there have been changes to the required documentation for these products following the entry into force of MDR and IVDR (Regulation (EU) 2017/745 and 2017/746), the working group was set up to offer our member companies a forum for exchange experiences and to discuss on issues related to the implementation of the above-mentioned regulations.

The working group meets on average every two months.

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13.2 WG Standard Marketing Authorisations (currently inactive)

The working group was set up at the end of 2021 in the light of the potential impact of the EU pharmaceutical legislation on standard marketing authorisations. The aim of the working group is to closely monitor the topic, react to changes and evaluate possible alternative authorisation routes. Special sub-working groups have been set up for the latter point.

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13.3 WG Text Amendments

The working group was initiated to discuss the expectations of the (supervisory) authorities with regard to the implementation of text amendments. The working group provides assistance to Pharma Deutschland member companies and also prepares documents and lines of reasoning, e.g. on processes in the pharmaceutical industry, which can be used as a basis for dialogue with the authorities.

The working group meets on an ad hoc basis as required.

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13.4 WG Variations

This working group supports member companies in the light of the changed legal framework for variations and the planned amendment to the Classification Guideline.

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13.5 WG Cooperation with the German national competent authorities

The aim of the working group is to jointly prepare a member survey on cooperation with the national competent authorities for human medicinal products (German: BOB) and also to facilitate knowledge-sharing between member companies. The survey is intended to generate data and identify key topics in order to address them in bilateral discussions with the BOBs.

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13.6 S-WG ePI Germany (see also 4.4)

This inter-association (BPI, Pharma Deutschland, VFA) sub-working group supports the German and European projects for the creation, storage and maintenance of electronic product information.

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14. Research and development

14.1 WG Clinical Trials of Pharmaceuticals and Medical Devices / Drug-device combinations (see also 9.6)

In the field of clinical research, Pharma Deutschland e.V. currently has a combined working group on the topic of “Clinical Trials”, which deals with general issues relating to clinical research with both areas, pharmaceuticals and medical devices, in Germany. The working group supports on a broad basis the development of legal texts at both German and European level; currently it has a particular focus on the implementation of the European regulations (MDR, Medical Device Regulation and CTR, Clinical Trials Regulation) in both fields. The working group also provides assistance to Pharma Deutschland member companies in explaining and understanding the content of the law and in implementing the regulations in practice.

The working group meets three times a year.

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15. Self-medication

15.1 Expert WG Switch

When active ingredients or pharmaceuticals are released from their prescription obligation to a pharmacy obligation, this is referred to as “switch”. The group develops strategies for the responsible expansion of self-medication, derives measures to improve the switch process and draws up proposals for political and public communication.

The Switch Expert working group is chaired by Dr Larissa Kremer (Sanofi/Opella) and Ms Berit Frei (Haleon) company).

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15.2 WG “Green prescriptions”

The working group coordinates and supports the “www.Pro-Gruenes-Rezept.de” initiative to promote “green” prescriptions (OTC recommended by the doctor). The aim of this initiative is to raise awareness among physicians for self-medication with over-the-counter medicines, strengthen the green prescription brand image and provide physicians with free-of-charge green prescriptions via the www.Pro-Gruenes-Rezept.de platform and to draw attention to use electronic green prescriptions.

The working group is assigned to the Market and Self-Medication Committee.

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15.3 WG OTC Medicines

The aim of the working group is to strengthen the overall perception of the intrinsic value of OTC medicines and OTC products, which are ideally dispensed in pharmacies to guarantee trustworthy information and appropriate care. The aspects of trust and image among stakeholders and the development of a policy for self-medication are of particular importance.

The working group is assigned to the Market and Self-Medication Committee.

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16. Special product groups, differentiation

16.1 WG Pharmaceuticals and Borderline Products

Close-to-pharmaceutical “health products” with food status are of interest to Pharma Deutschland member companies for several reasons. There have always been pharmaceutical manufacturers who supplement their portfolio of pharmaceuticals with products from other legal areas. In addition to medical devices and cosmetics, these are primarily food supplements, foods for special medical purposes, novel foods and biocides. The association offers the members of the working group an information and discussion platform. A separate newsletter reports on current developments that are relevant to the above-mentioned areas. But also in the interest of medicinal products, it has become increasingly important to follow developments in related legal areas in order to identify influences on the pharmaceutical sector in a timely manner.

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16.2 WG Medical Cannabis

This working group deals with current issues relating to the pharmaceutical quality and quality assurance (GACP, GMP, GDP) of medicinal cannabis. Issues relating to regulatory aspects as well as the handling of cannabis-based prescription and bulk formulation pharmaceuticals are further topics that the working group deals with.

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17. Sustainability

17.1 WG Packaging

The working group supports the work of the Sustainability & Climate Protection Committee and deals with issues that arise in the context of new legislative procedures.

These include in particular topics relating to the circular economy and design for recycling, increasing the recyclability of packaging materials, the use of recyclate and analysing new regulatory requirements.

In addition, the Packaging working group supports the committee and examines where concrete approaches can be identified to accelerate the switch to recyclable primary packaging in the pharmaceutical sector.

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17.2 SG Nagoya (currently inactive)

On 12 October 2014, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation and the associated EU Regulation No. 511/2014 came into force.

As the provisions of the Nagoya Protocol and the associated European and German legal regulations are also relevant for manufacturers of medicinal products, the Nagoya study group deals with issues relating to the implementation of the Nagoya Protocol and the corresponding regulations. Among other things, a recommendation on the implementation of the Nagoya Protocol was developed and published in cooperation with the Federal Agency for Nature Conservation.

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