

# Pooling Project Pharmacovigilance

Comprehensive pharmacovigilance solution



Literature Searches  
PSUR Compilation  
Pharmacovigilance  
Database  
SOP-Online  
Friendly Audit  
Training / Coaching





# Pooling Project Pharmacovigilance

## Comprehensive pharmacovigilance solution

In close cooperation with pharmaceutical firms, the BPI Service GmbH launched the Pooling Project Pharmacovigilance in 2005. The pooling concept at the core of the project - to provide access to information and services relevant to pharmacovigilance in a generic fashion, independent of a specific firm or product - allows participating firms to fulfill the regulatory requirements for pharmacovigilance activities efficiently and at a lower cost.

The service spectrum of the BPI Service GmbH includes:

- continuous **literature searches and evaluations** based on active substances
- compilation of **Periodic Safety Update Reports (PSURs)**
- maintenance of a **joint E2B-compliant database (BPI-Pheda)** for the administration, retention and electronic transmission of adverse reaction reports
- templates for **Standard Operating Procedures (SOPs)**
- conduct of „friendly audits“
- focussed **training and continuing education courses** as well as **coaching** of staff on pharmacovigilance-specific topics

## Summary of Project Benefits

- **cost reduction** and **transparency** through „pooling effect“
- service modules can be **individually ordered**

- **user-friendly** software tools
- **comprehensive Quality Management** – i.e. validation, SOPs
- maximum **synergies** between various service modules
- **ongoing development and improvement** of service modules in cooperation with customers
- **interdisciplinary** project team
- in-depth **industry and regulatory expertise** - close ties to the German Pharmaceutical Industry Association (BPI) e.V.

## Who may use the services?

The varied pharmacovigilance-specific services of the BPI Service GmbH are available to **all marketing authorisation holders (MAH)** - membership in the German Pharmaceutical Industry Association e.V. is not required.



## For more information ...

... please visit our websites

[www.bpi-service.de](http://www.bpi-service.de)

[www.psur.de](http://www.psur.de)

[www.pharma-sop.de](http://www.pharma-sop.de)

... or simply order our free German-language Pharmacovigilance Newsletter.

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# Literature Searches and Evaluations

- **Continuous** searches in **more than ten databases**
- **Weekly or monthly** searches available
- **Active substance-specific** searches on **chemically defined, plant-based and homeopathic substances**
- **Cursory evaluation** of identified literature based on current German regulatory requirements
- **Clustering** of search results into three groups: „**Potential Cases**“, „**PSUR-relevant**“ and „**Others**“
- **Online user-database** for viewing the literature entries
- **Automatic email-alerts** when new literature entries are posted in the database
- **Optional additional services for literature cases**
  - **line listings**
  - **CIOMS forms** (incl. recommended assessment)
  - **XML** (E2B-compliant files for electronic transmission)

# Periodic Safety Update Reports (PSURs)

In response to the specific needs of the individual pharmaceutical firm, the BPI Service GmbH offers both customized (submission-ready) PSURs as well as generic, active substance-specific “pooled” PSUR templates. All PSURs are delivered in an editable digital format.

## Customized PSURs

Compilation of **complete, customized PSURs** in accordance with Volume 9A for submission to regulatory authorities. These PSURs include

- **narratives** for literature cases
- **Line Listings** for literature cases
- **published studies**
- **company-specific information** such as **direct reports, sales figures and authorization data** including narratives, Summary Tabulations and Line Listings
- **bibliography**

## „Pooled“ PSURs

Compilation of **active substance-specific PSUR-Templates** (additional cost reduction when these are ordered by multiple companies). These include

- comprehensive suggested **text modules**
- **narratives** for literature cases
- **Line Listings** for literature cases
- **published studies**
- **Summary Tabulations** for literature cases
- **bibliography**



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# Pharmacovigilance Database (BPI-Pheda)

- **E2B-compliant database** for electronic transmission and administration of adverse reaction reports (ICSRs/SUSARs)
- **Transmission via gateway**
- **Autonomous administration and electronic transmission by users** within their own account
- Space for **retention and administration of non-reportable case reports**
- **Specific data queries and evaluations**
- **Generation of tables for reports** – e.g. PSURs, Annual Safety Reports

- **Integrated MedDRA Browser** for coding of adverse reactions
- **Free support hotline**
- **Support for EudraVigilance registration**
- **Password protection of company data**
- **User-friendly** user interface
- Database is owned by the BPI e.V. and **independent** of a commercial service provider
- **Software installation** by user not required - „Software-as-a-Service“
- Fully **validated system** – according to GAMP-standards
- Option to participate in a **MedDRA group license** – license is maintained by BPI Service GmbH (e.g. negotiations with MSSO, support for tax exemption)
- **Transparent cost structure** – costs are calculated based on the number of reportable case reports
- **Additional service tools**
  - training courses available in English and German
  - creation and transmission of case reports



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# Standard Operating Procedures

(German-language)

## SOP Templates

- Contain text modules and process descriptions
- Generic structure allows easy customization to fit individual requirements

## Templates for referenced documentation

- Templates to assist in compiling documentation described in the SOPs
- Can be used as master templates for **implementation** and/or **improvement of an in-house SOP-system**
- May be ordered in **addition** to the main SOP

## Topics covered

- Validation of computerized systems
- Pharmacovigilance
- Clinical trials

Supplied as **CD-ROM** in an editable **format** (RTF, Word) to allow individual adjustments by user



# Friendly Audits

Pharmacovigilance-specific „**friendly audits**“ as part of a company’s **quality management system**

**Analysis** - systematic review and evaluation based on checklists - of the in-house **pharmacovigilance system (structure, processes etc.)** in the context of regulatory requirements with emphasis on

- existing documentation (SOPs, Organigrams, Workflows etc.)
- documentation and handling of adverse reaction reports (ICSRs, SUSARs etc.) and other reports (PSURs, Annual Reports etc.)
- databases
- analysis of external and internal interfaces (e.g. SOPs, service provider and consultant contracts, consumer and health professional information)
- staff interviews

Identification of **areas for improvement/potential optimization**

Generation of an **audit report** as well as an **action plan** for rectification of possible findings



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# Training / Coaching

## Training

- **Customized workshops (in-house training)** in the form of initialization workshops and specific focus workshops
- Cooperation with **Colloquium Pharmaceuticum** GmbH a subsidiary of the BPI Service GmbH - in the context of a **continuing education curriculum „Pharmacovigilance“**

## Coaching

- **Service hotline** providing support to pharmacovigilance staff regarding **medical and regulatory questions**
- Professional support in the **revision of documents** generated by client

# The BPI Service GmbH

**Your Partner in the Healthcare Marketplace**

The BPI Service GmbH was founded as a subsidiary of the German Pharmaceutical Industry Association (BPI) e.V. in 1991. From the beginning, the BPI Service GmbH has drawn on its in-depth knowledge of the healthcare sector and focussed on the requirements of stakeholders in the national as well as international healthcare sectors by offering a product portfolio of consulting and services based on those requirements.

## Maximizing synergies with a portfolio of interconnected services

### ■ Communication in Healthcare

Press and media | Online- / Offline-Publishing | Communications consulting | Event management

### ■ Pharmacovigilance

Literature Searches | PSUR Compilation | SOP-Online | BPI-Pheda | Friendly Audit | Training / Coaching

### ■ Specialist Compendia

Pharma Kodex | Special focus publications | Contract templates

### ■ Education and Training

Congresses / Symposia | Workshops / Intensive seminars | In-house training



**For more information,  
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**[www.psur.de](http://www.psur.de)**  
**[www.coll-pharm.de](http://www.coll-pharm.de)**



## Our Strengths - Your Success

- **Interdisciplinary team**  
(physicians, pharmacists, lawyers,  
business economists, journalists)
- In-depth **expertise** in the healthcare sector
- Many years of experience
- Powerful **network**
- **Full-service provider**  
with modular service portfolio
- Excellent value for money

**Please do not hesitate to contact us!**

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