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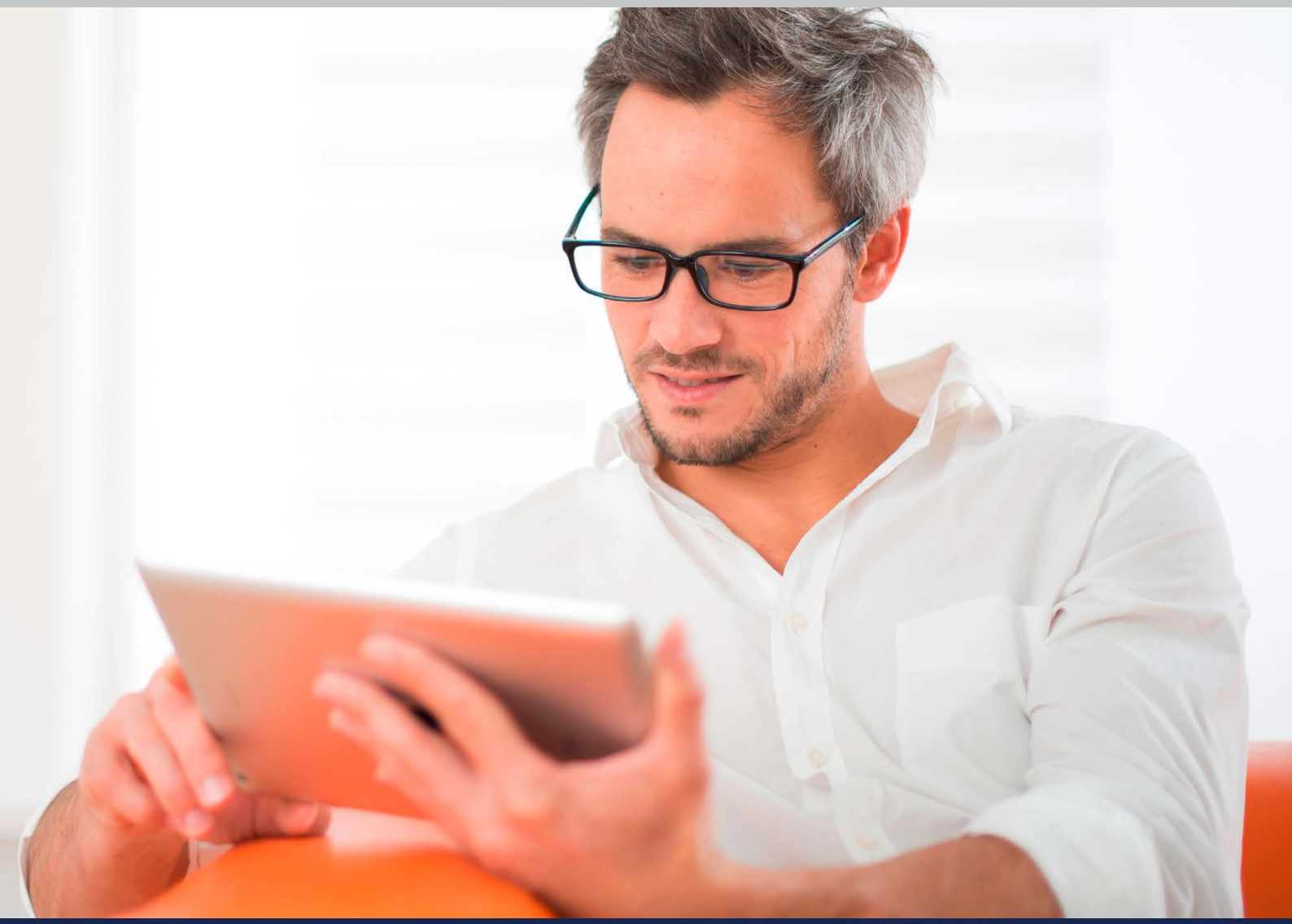


GMP audits and inspections

Jürgen Ortlepp

Dear Readers

We are pleased that you are interested in this whitepaper. In the following, you will gain valuable insights, tips and recommendations for your job. You will receive the latest, practical trends and impulses directly from our expert.

In addition, you can use our offer and deepen your specialist knowledge with our range of offers and deepen your knowledge.

We wish you many new insights while reading.

About the author

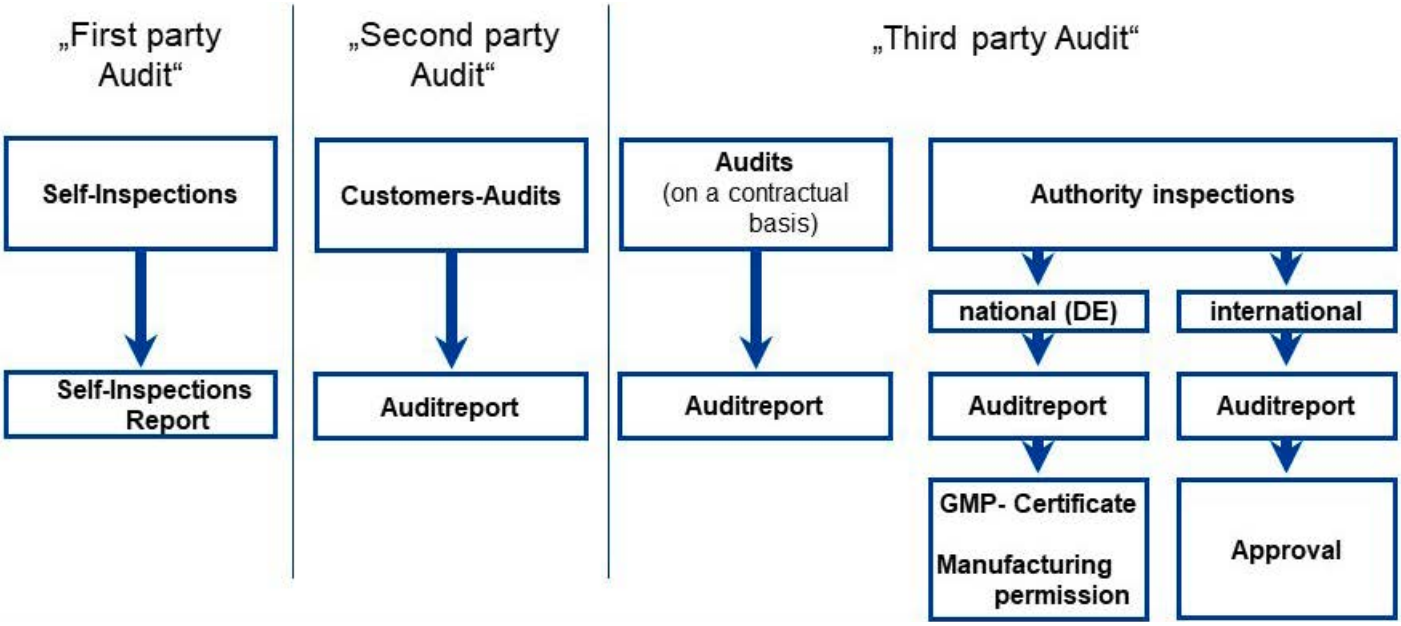
Jürgen Ortlepp – Bayer AG, Leverkusen, Germany
worked for Infraserv Logistics GmbH until April 2022, first as GMP Officer, then as Head of Quality Safety Hazardous Goods/GMP, and since 2018 as Business Unit Manager Special Processes and Quality Management.

He has been a GMP/GDP expert and auditor as well as a GMP/GDP trainer and coach in the field of APIs and finished pharmaceuticals for many years and holds lectureships on process management and good practices (GxP) as well as quality and service management at various universities of applied sciences.

GMP audits and inspections

- Definition of terms and audit types
- Regulatory basics
- Typical audit focuses

Audit types („Who audits“)



- **General GMP inspection ➔ System audit**
  - „QMS audit“
- **Product related GMP inspection ➔ Product audit**
- **Process related GMP inspection ➔ Process audit**
  - „Tour through the process chain“
- **PAI – Pre Approval Inspection)**
- **Partial inspection, re inspection**
- **Occasional GMP inspection**
  - „audit for cause“, for example complaints, deviations

Regulatory requirements

AMWHV § 11 „Self-inspections and supplier qualification“ / EU GMP Guideline, Chapter 9 „Self-inspections“

- **Implementation in practice: Open Book (discover all weaknesses within a system)**
- **Risk-based process defined in SOP (annual planning)**
- **Forms for report and observations / deficiencies**
- **Effectiveness review of measures**
- **Planning, execution and tracking possible via database**

Regulatory requirements for service providers + suppliers

- **AMWHV § 9 „Outsourced activities“**
- **EU-GMP-Guideline, Chapter 7 „Outsourced Activities“**
  - Implementation in practice
  - Questionnaires / audits / ongoing supplier evaluation by QA
  - Technical Agreements / Quality assurance agreements
  - Labeling of the goods, identity / release tests (analytical laboratory)
  - Complaint processing
  - Qualification of the third party

Regulatory requirements for authority inspections

Guideline 2001 / 83 / EG of the European Parliament and of the Council on the Community code relating to medicinal products for human use Article 111: The competent authority of the Member State concerned shall satisfy itself, by means of repeated and, if necessary, unannounced inspections and, where appropriate, by carrying out spot checks entrusted to an Official Medicines Control Laboratory or to a laboratory designated for that purpose, that the legal requirements relating to medicinal products are being complied with. [...]

AMG § 64 Implementation of monitoring

Establishments and facilities in which medicinal products are manufactured, tested, stored, packaged or placed on the market or in which they are otherwise traded are insofar subject to supervision by the competent authority; the same applies to establishments and facilities that develop medicinal products, clinically test them, subject them to residue testing or acquire or use medicinal products pursuant to Section 47a (1), first sentence, or medicinal products intended for use in animals. The development, manufacture, testing, storage, packaging and placing on the market of active substances and other substances intended for the manufacture of medicinal products and of tissues, as well as other trade in these active substances and substances, shall be subject to supervision, insofar as [...]

General documentation / process description

- QM system / responsibilities / organizational charts
- Training documents / training organization
- SOPs
- Qualification/validation plans
- Supplier qualification
- CAPA system
- Document control
- Quality assurance agreements / contracts with third parties

General documentation / process description II

- Safety and company safety organization
- Industrial and personal hygiene
- Procedure for analysis and calibration deviations (OOS, OOC)
- Retention samples
- Devices / plants
- Handling of raw materials / auxiliary materials
- Handling of packaging materials
- Access control
- Pest Control

Quality recordings

- Deviation reports
- Change Control
- OOS findings
- Calibration records
- Maintenance/Repairs
- Risk analyses
- Complaints

Other offers:

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