

# The role of PSURs in pharmacovigilance inspections – Getting it right and practical experience

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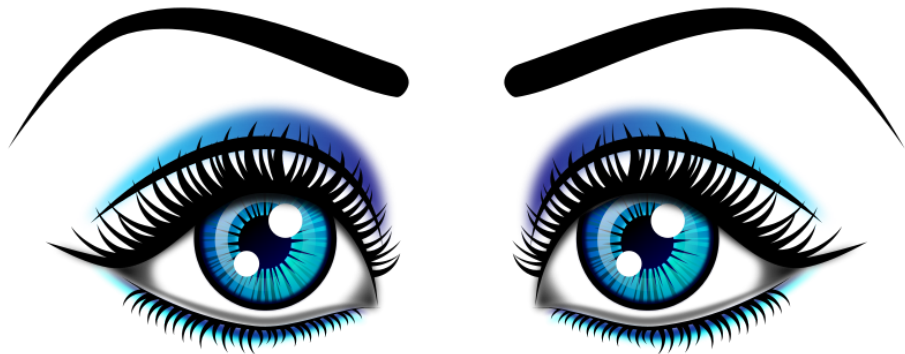
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# Agenda

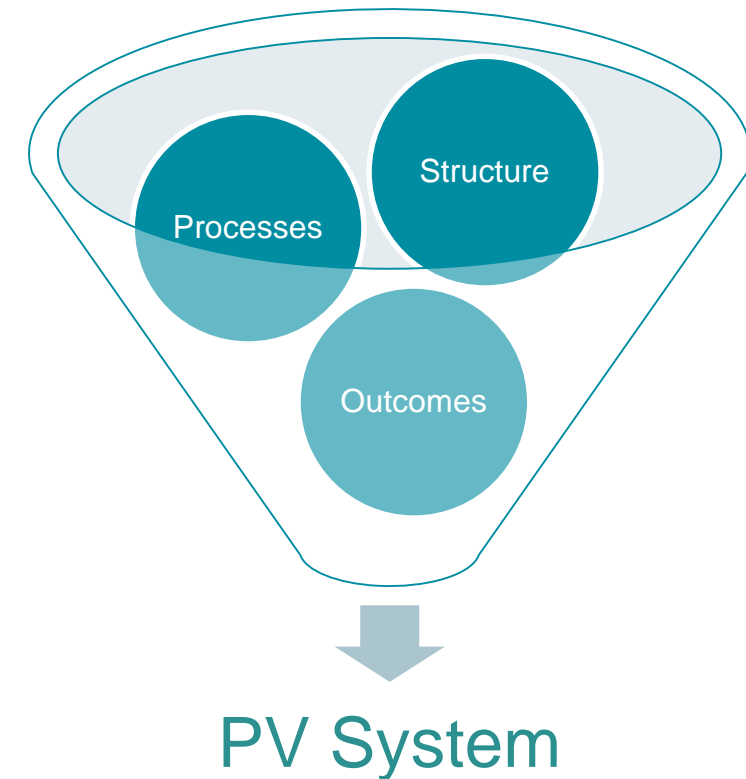
- ▶ Why are PSURs important
- ▶ PSURs and inspections
- ▶ Hints and tips
- ▶ Conclusion

# Why PSURs are important

- ▶ The eyes are a window to the soul

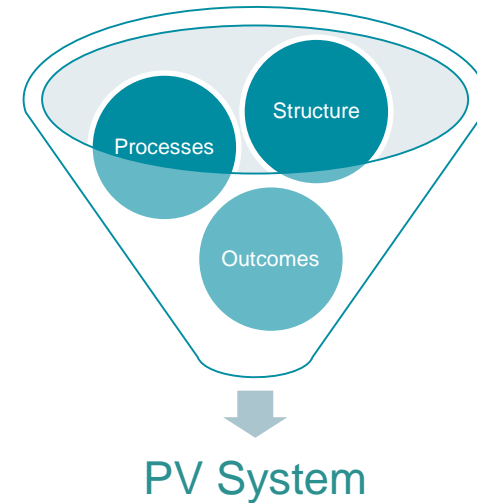


- ▶ The PSUR is the window to your PV system



# What do we need to demonstrate a robust PV system?

- ▶ **Consistency**
  - With legislation
  - With our described processes
  - With each other
- ▶ **Good documentation**
  - Processes need to be clearly written
  - Evidence of decisions and actions need to be kept
  - Signatures, dates, version numbers
- ▶ **Oversight and Governance**
  - Awareness of what is going on
  - Rapid actions to address issues
  - Clear communications



# PSURs and Inspections

## ▶ Good PSURs demonstrate

- Effective signal management
- Robust decision making
- Timely communication
- Strong cross-functional working
- Good documentation practices
- Efficient PV processes
- Overarching QPPV oversight

## ▶ Poor PSURs might imply

- Misaligned processes
- Silo working
- Ineffective governance
- Poor document management
- Delayed communication
- Incomplete data review
- Lack of QPPV awareness

# PSURs and Inspections

- ▶ Tell me the process ....
- ▶ ...Show me the process....
- ▶ ...Show me the evidence

# Tell me the process

- ▶ Inspectors want to speak to staff who actually 'do' the process rather than a 'process expert'
- ▶ Not just PV staff but other cross-functional contributors too
- ▶ Staff need to be able to clearly articulate the process they follow to produce a PSUR
- ▶ Need to demonstrate that they have a robust, consistent approach, they understand the data and they know how their contribution / section fits into the whole document
- ▶ Must demonstrate clean hand-offs to other team/function
- ▶ Will want to hear reference to process, review, governance and documentation



# Show me the process

- ▶ SOPs covering each step of production of PSURs
  - Data retrieval
  - Writing
  - QC
  - Review / approval
  - Submission
- ▶ Detailed work instructions and guidance to ensure consistency
- ▶ Validated search strategies
- ▶ Details of qualification and training of all contributors, reviewers, approvers and submission staff involved

# Show me the evidence

- ▶ Training slides and evidence of training
- ▶ Data outputs and inputs
  - Case listings and tables
  - Previous commitments
  - Signals
  - Exposure data
  - Literature & Studies
- ▶ Meeting minutes
- ▶ Completed QC checklists
- ▶ Evidence of review and approval
- ▶ Evidence of QPPV oversight
- ▶ Submission tracking and metrics
- ▶ Quality metrics

# Quality Management

- ▶ PSURs production is a critical process
- ▶ Have measures of 'quality' as well as 'timeliness' (in PSMF)
- ▶ Should be subject to regular audit (including audit of service providers)
- ▶ Evidence of Corrective and Preventative Actions taken should be available
- ▶ Essential to show evidence of effectiveness of CAPA actions

# Inspection preparation

- ▶ Ensure all cross-functional staff are aware of the importance of PSURs and their role
- ▶ Make sure they know the process and can speak to it
- ▶ Have evidence of training to hand
- ▶ Have access to records of meetings, discussion, decisions, approvals
- ▶ Understand metrics, what has impacted them and what actions have been taken

# Key Takeaways

- ▶ PSUR is your 'license to operate'
- ▶ Monitoring and testing (audit) essential
- ▶ Cross-functional contributors are key players
- ▶ Tell me the process – Show me the process – Show me the evidence

Inspection readiness is a culture not a process

Ask

