AI in Auditing

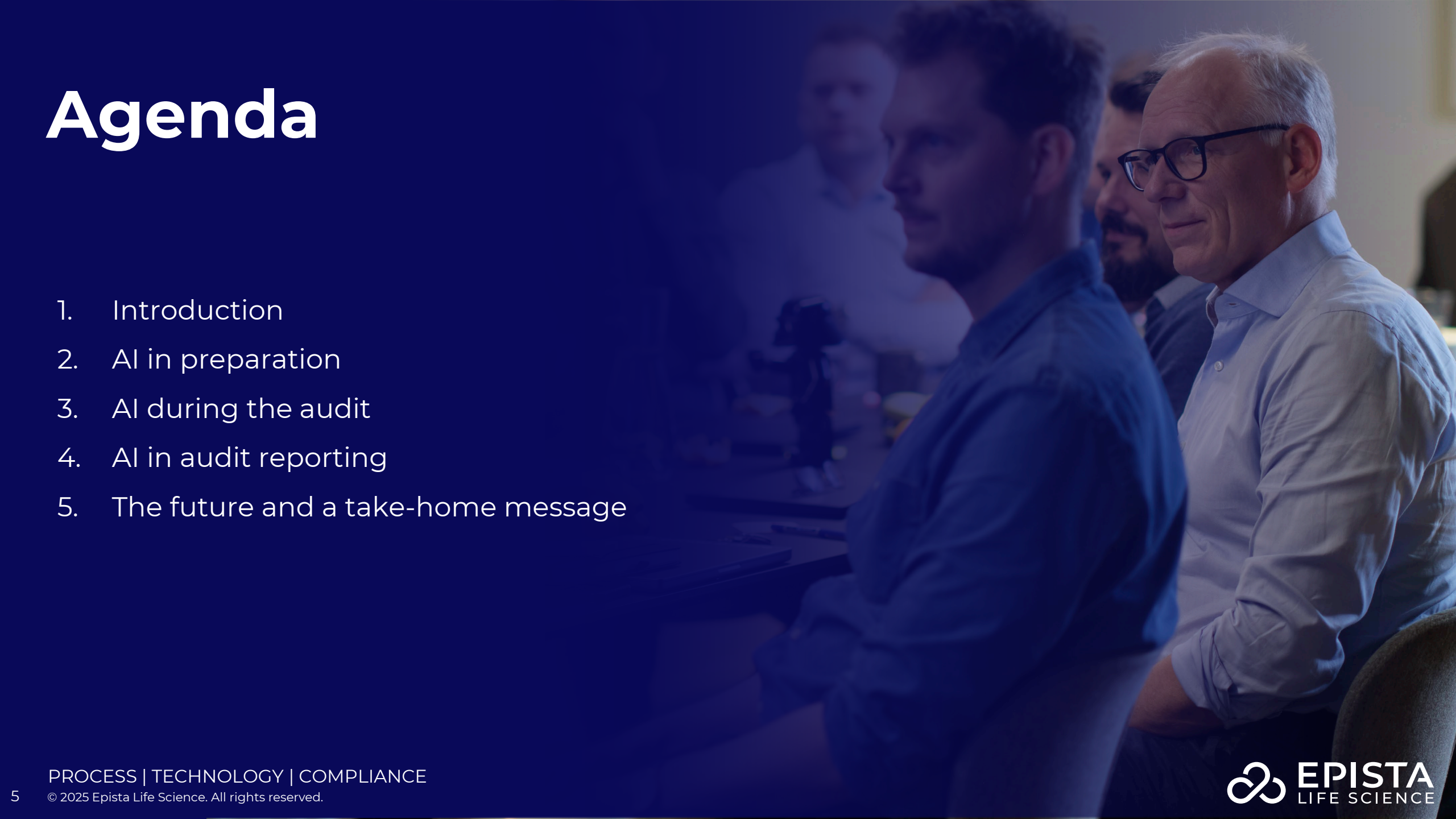
22th of October 2025

SARQA CONFERENCE

EPISTA LIFE SCIENCE

Agenda

1. Introduction
2. AI in preparation
3. AI during the audit
4. AI in audit reporting
5. The future and a take-home message



Disclaimer

- This, like an audit is a snapshot of the current situation.
- AI improves fast. Be on the train!

AI in Preparation

”Administrative Intelligence” or more?

PROCESS | TECHNOLOGY | COMPLIANCE

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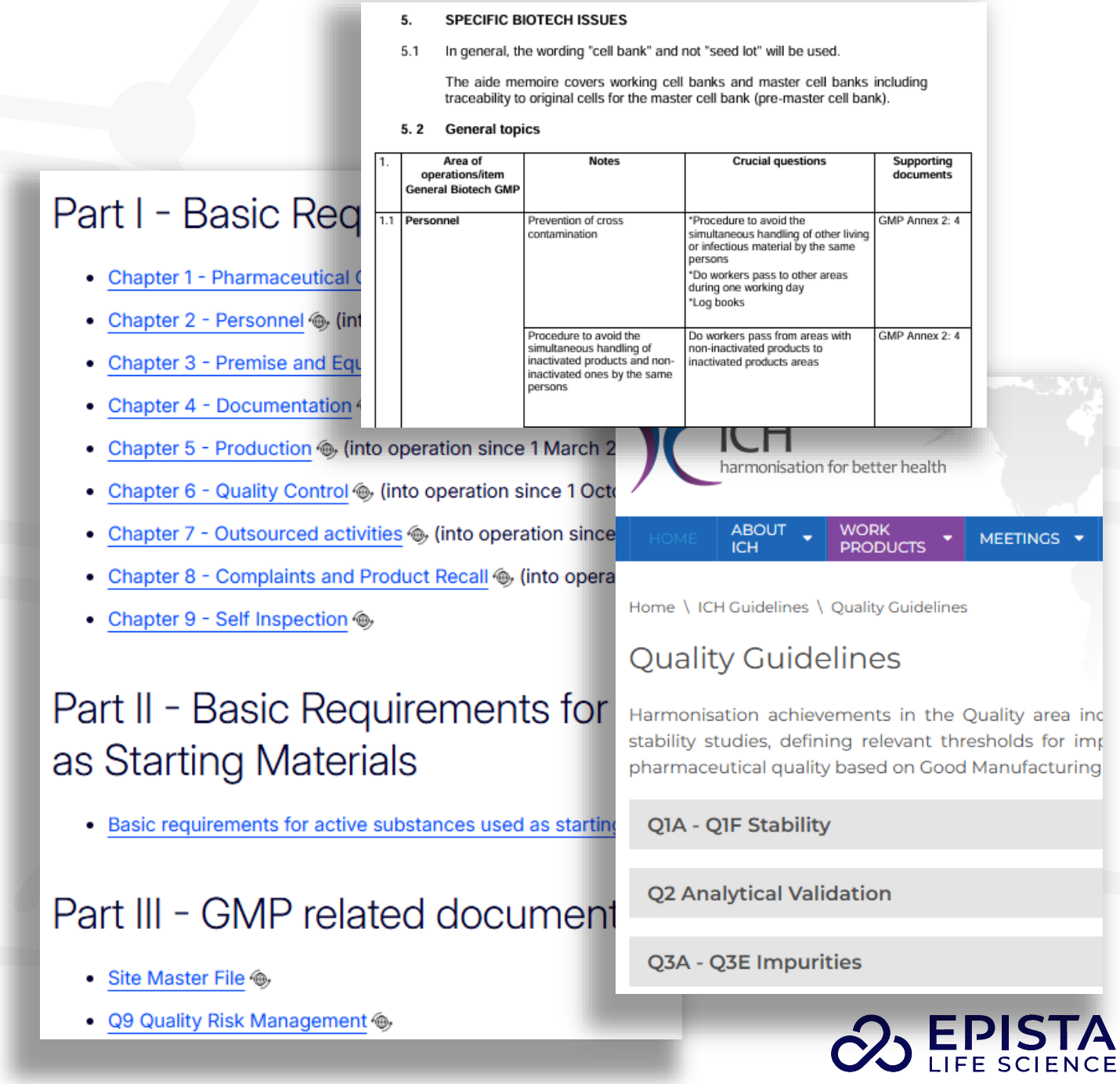
AI in preparation

Audit plan and agenda.
- Often based on a good template
- Use AI to feed it

Focus on content:
- Checklists
- Regulatory criteria

Performance
- Soft skills



AI with Checklists

I am going to make a GMP audit of a biological API manufacturer. The manufacturing includes upstream and downstream manufacturing and the final Drug substance is freeze dries. THe company makes its own pharmaceutical water and the manufacturing is in Cleanrooms of Grade D and C, virus inactivation and removal is a necessary part of the manufacturing. There is also a QC laboratory with both chemical and microbiological testing included in the scope. Could you make me an audit checklist covering these activities based on PIC/S Aide memoires and FDA inspection Checklists?

Thought for 32s

Absolutely—here's a focused, practical **GMP audit checklist** tailored to a **biological API** manufacturer with **upstream + downstream**, **virus inactivation/removal**, **freeze-dried drug substance**, **PW/WFI generation**, **Grade C/D cleanrooms**, and **QC (chem + micro)**. It follows the spirit of **PIC/S Aide-Mémoire** and **FDA inspection playbooks** (structure, evidence, and risk emphasis).

Audit Checklist — Biological API (Upstream, Downstream, Viral Safety, Lyophilized DS, PW/WFI, Grade C/D, QC)

1) Quality System & Governance

- **Org/independence:** Clear roles; QA independent from Production/QC; escalation paths.
- **PQS elements:** Deviation/CAPA, Change Control, Risk Management (ICH Q9), Management Review.
- **Data integrity:** ALCOA+, audit trails (HPLC, EM systems, LIMS, balances, spreadsheets).
- **Supplier/outsourcing:** Qualification, technical/quality agreements, performance monitoring.
- **Training & gowning:** Role-based curricula; aseptic/biological hazards; media-fill where applicable to DS handling; qualification & requalification.

  Records to see: Site Master File (or equivalent), Quality Manual, last 12–24 mo. KPIs, APR/PQR (if used), deviation/CAPA logs, quality review minutes.

2) Facilities, Cleanrooms & Contamination Control (Grades C/D)

- **Zoning & flows:** People/material/equipment/ waste flows; segregation (cell culture vs purification vs virus steps); unidirectional movement; pass-throughs.
- **HVAC/pressure:** Qualified differentials, airflow p↓rns, recovery, alarms; Grade transitions C↔D; smoke studies where relevant.

Turning a Checklist into an Agenda

Thanks could you turn the checklist into an agenda for a two-day audit for two auditors following two different tracks after a common tour of the facility?

Perfect — let's turn your checklist into a **structured two-day audit agenda** with two auditors, running in **parallel tracks** after a common introduction and site tour.

🗓️ Two-Day Audit Agenda – Biological API Manufacturer

Day 1 (Morning) – Joint Opening & Tour

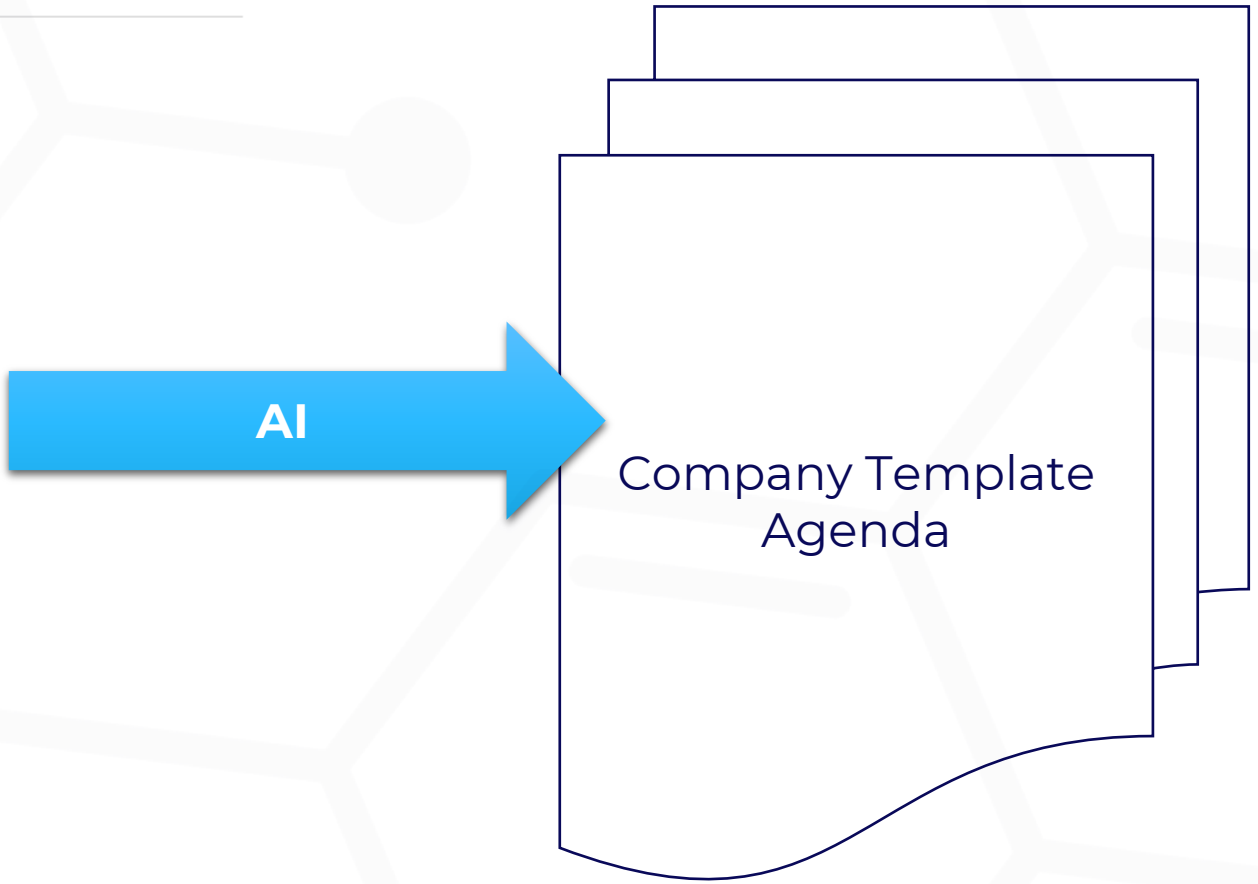
08:30 – 09:00

- **Opening Meeting** with management and QA.
- Introduce audit team, scope, objectives, and agenda.

09:00 – 11:00

- **Facility Tour (both auditors together)**
  - Warehousing (materials, disposables, chemicals).
  - Pharmaceutical water generation & distribution (PW/WFI).
  - Cleanroom areas (Grade D → C).
  - Upstream bioreactors, downstream chromatography areas.
  - Viral inactivation/removal suites.
  - Lyophilization equipment.
  - QC laboratories (overview only).

11:00 – 11:15



AI and the soft skills during an audit

I am going to make the audit of the biological API manufacturer on a site outside Hyderabad in India. We are wo auditors going, one man and one woman. We are both from Sweden. Are there any cultural and workplace norms or differences to Swedish norms and values we should be aware of and consider in order to get good cooperation and truthful answers to our questions during the audit?

4. Saving Face & Avoiding Embarrassment

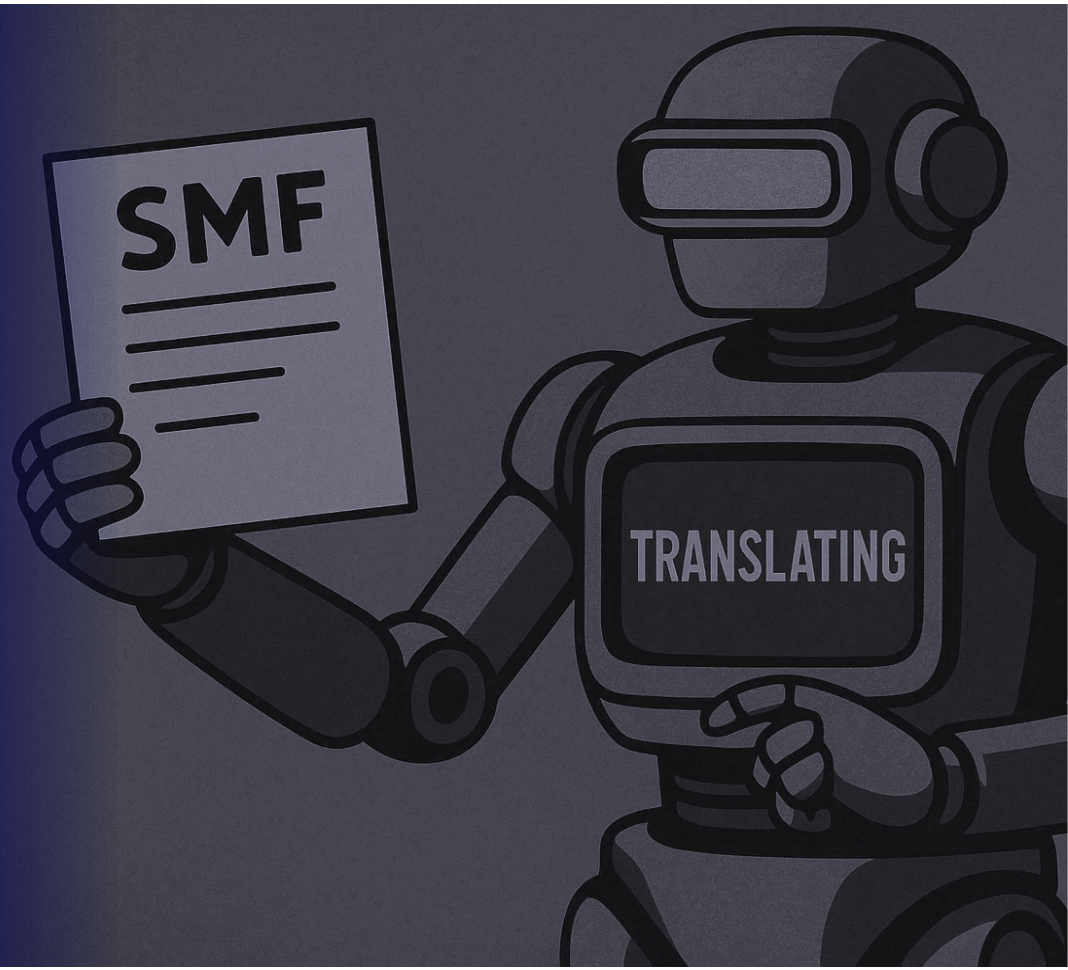
- **India:** Strong cultural value — employees avoid admitting errors or gaps openly, especially in front of peers/managers.
- **Sweden:** Admitting problems early is seen as responsible.

Audit Tip:

- Don't put individuals on the spot in front of their boss.
- Frame findings as **systemic** rather than personal ("How does the procedure ensure consistency?" instead of "Why did you fail to...?").
- Give positive feedback where it's due — builds trust and balance.

AI to summarize the Site Master File
- and other documents sent as preparation for the audit

- I don’t do it
- Non-disclosure and legal reasons
- Only with a secure internal AI
- This is where I want to spend my preparation hours, in the details



AI during the audit execution

”Liberating your brain”

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Cognitive overload

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Remote audits

If client allows – turn recording and transcription on

- Be sure to summarize findings before going to a new subject
- Have AI turn the transcription into a narrative – But review!

On-site audits

Currently, very little help – I don’t use AI here today, but you could:

- Use phone where possible for recording – transcription
- AI glasses – future possibility, but with limitations

AI during reporting

PROCESS | TECHNOLOGY | COMPLIANCE

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Writing the report

- Formalities
- Narrative

Spend as little time as possible
Use AI and the auditee

- Findings/non-conformities
- Conclusion

Spend as much time as possible

Beware of seductive AI lying or hallucinating!

When using HVAC for Cleanrooms in aseptic procssing in the pharmaceutical industry is it adviceable to have sepatate HVAC-systems for cleanrooms of different gfares or could one HVAC-system provide air for more than one cleanroom-grade. Please present any references or proof you find for either of these options.

1. EU GMP Annex 1 (2022)

Correct Annex, correct chapter

Key paragraphs on HVAC systems:

- **5.2 Premises design:**

  > "There should be an appropriate flow of materials and personnel to minimise the risk of contamination."

5.2 etc. exists but ...

- **5.3 Air supply systems:**

  > "Air supply systems should be designed to minimise the risk of contamination of the product... The quality of air in clean areas should meet the appropriate classification (e.g., Grade A, B, C, D)."

- **5.6 & 5.7 Airlocks and interconnecting areas:**

  > "If areas of different classifications are adjacent, the air handling system should be designed to prevent cross-contamination."

- **5.19–5.20 (HVAC):**

  > "HVAC systems must be designed so that the air quality of higher classified areas is not compromised by adjacent lower-classified areas. Where possible, separate air supply systems are recommended for areas of differing grades."

5.19-20 does not exist!

✅ **Interpretation:**

- Annex 1 **recommends separate HVAC systems** for cleanrooms of different grades when cross-contamination could be a risk.
- It does **not mandate** separate systems in all cases; the requirement is risk-based. You can have a single system **if the design ensures proper airflows, differential pressures, and filtration so that contamination cannot flow from lower to higher grades**.

What would've happened if I were in a hurry or didn't know my Annex 1?

Where are we headed?

- The technology evolves fast
- Assistance during the execution
- Translation – live and documents
- IP security needs to be addressed/solved
- The auditor role is not easily replaced!

Thank you!

Questions at the end!

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