



:Session 4: Risk assessment for aseptic techniques/practices

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Aseptic Processing Workshop:
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Connecting People, Science and Regulation



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Xellia Pharmaceuticals

- Masters in Microbiology from IIS, Aurangabad
- 34 years in Pharmaceutical industries
- Long Terms :
 - Lupin (14 Y);
 - Strides (13 Y);
 - Wockhardt (2 Y);
 - Xellia (4 Y) ;
- Short Terms : Hindustan Antibiotic ; Almet ; Ajanta Pharma ; Intas pharma
 - Projects of sterile formulations & Regulatory guidelines;
 - Techno-commercial activities
 - Implementing cost reduction initiatives.
 - Exposure in US FDA, MHRA, ANVISA, MCC, WHO, TGA & NDA Regulatory inspections & audits.
 - Due diligence / Compliance audits / Regulatory audits & vendor development

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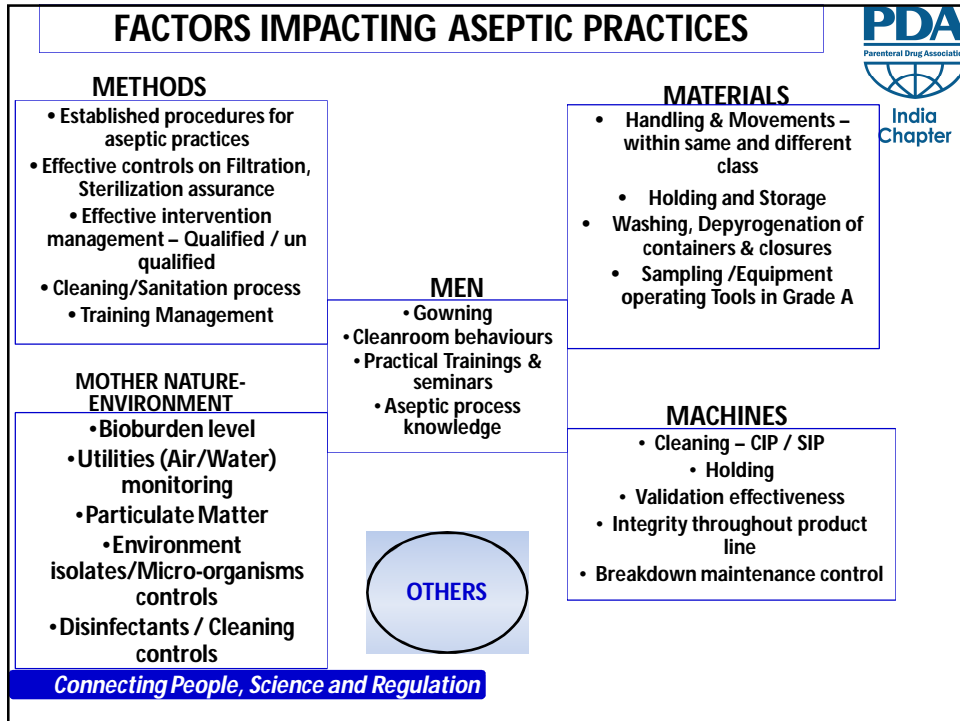
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- **Anyone**, who don't Know Risk Assessment / its procedures & Tools ?
- **Any company**, that doesn't perform Risk Assessment/s?
- **Periodic Reviews**, on Risks/Failures (CAPA /Deviation/s) ?
- **Reassessment** of Risk areas (Aseptic practices)?
- **SOP's** are demonstrable for practice/s?

If YES...

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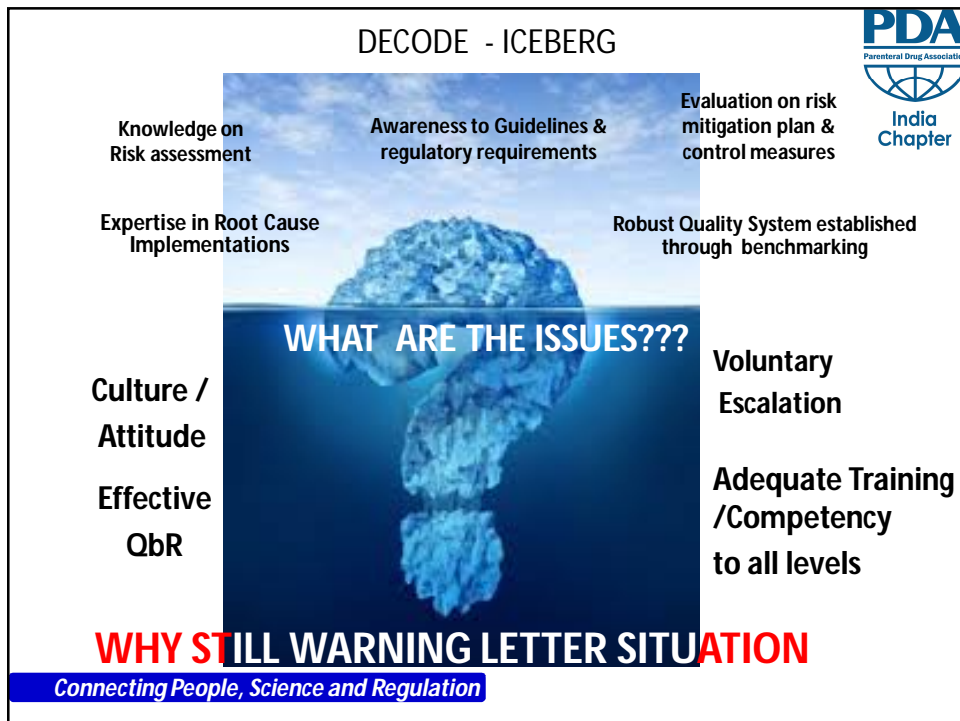


MOTHER NATURE-ENVIRONMENT

- Bioburden level
- Utilities (Air/Water) monitoring
- Particulate Matter
 - Environment isolates/Micro-organisms controls
- Disinfectants / Cleaning controls

OTHERS

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Thank You

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