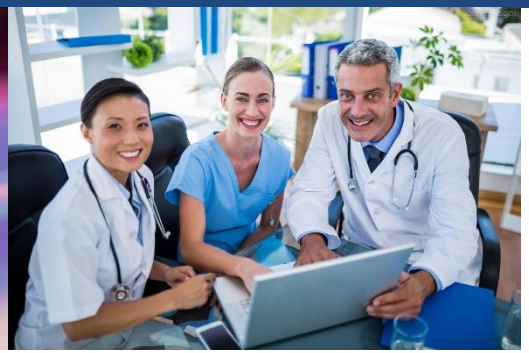
ICH implementation in Drug Manufacturing Area





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Joining ICH is of great significance to the high-quality development of China's pharmaceutical industry

Journey for Future Continuous Manufacturing (CM)

- Multiple MNCs have been engaged in the development and implementation of CM since 2004 for improving the efficiency, agility and flexibility of drug manufacturing.
- The first of Janssen product with Continuous Manufacturing technology at Puerto Rico site received FDA approval in 2016.
- Xian Janssen explored the CM opportunity and started the journey at new site design in 2015. Started integrated automation system since 2019 and keeps PAT studies.

Individual system applications to build up the CM fundamental experience

- Process Data, from integrated automation manufacturing system → CPP/PP trend report, alarm management.
- PAT (NIR) pilot for Loss of Drying monitoring in granulation.
- PAT (NIR) pilot for
  - Tablet Assay
  - Tablet Content Uniformity
- Multivariate analysis (MVA) is applied to investigations.

- ICH Q8, Q9 and Q10 guidelines are fully applied to the design process and ongoing implementation.

Proactive communication with regulatory agencies for innovative solutions.

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More opportunities of ICH Q9 and Q10 in continuous deployment

- Would support to embed the concept of ICH Q9 quality risk management and ICH Q10 Pharmaceutical Quality System to regulation setup and market supervision implementation.
- Risk based approach and quality management system approach will accelerate the launch of new innovative drugs to Chinese patient.