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## **Data integrity, quality by design and regulatory compliance**

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The objective is to bring out knowledge and new ways and avenues of learning and update on the latest trends and techniques in regulatory compliance environment. Data integrity is today's industry concern. Regulatory inspectors are focusing on data integrity aspects. The presentation covers the topics: (1) Root cause analysis by Fishbone Diagram (Ishikawa)-cause and effect diagram, case study for effective CAPA (Corrective and Preventive Actions), (2) importance of data integrity (DI) policy and internal audits, (3) cost of poor quality, (4) importance of quality culture, (5) quality by design concepts, (6) how to use six system concepts effectively during the audits and (7) tips for successful regulatory inspections.

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