



# e-CTD Experience

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Bonnie Southorn

Director, Core Technical Documentation and  
Submissions

Genpharm Inc.



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- Merck Generics preparing for eCTD
  - Not filed yet
- Currently publish from PDF Documentum based platform
- XML tools input from regulators to ensure compatibility



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- Challenges
  - Third party documents scanned if signatures required e.g. batch records or specifications
  - New technology – e.g. XML
- Transition
  - Set up electronic system to publish straight to eCTD
- Advantages
  - Life cycle management
  - Only if all changes also submitted electronically