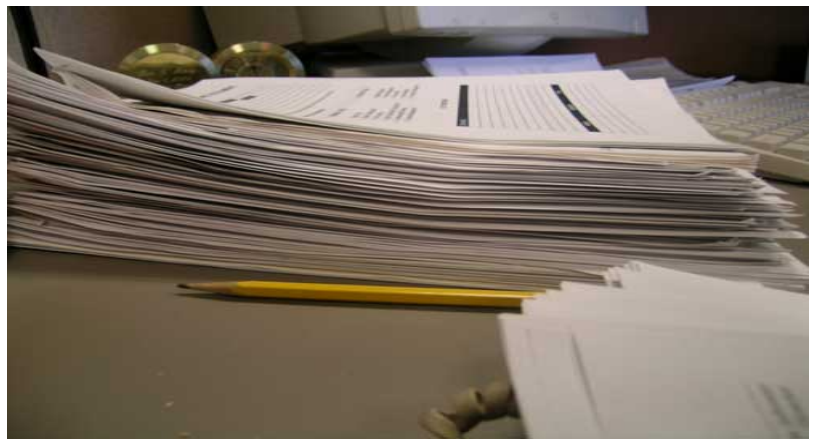
Recurring and Emerging Review Challenges in BGTD…



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Recurring Challenges

Documentation

- Cover letter does not adequately outline the scope of the submission
- Old submission filed in Canada without any updates
- QOS/CPID don't reflect the submission
- QOS not provided as a complete Word Document

- Change control in the Canadian context is not considered




Recurring Challenges

Paper Review

- Validation summaries don't contain adequate detail to allow reviewers to make scientifically-based decisions
- Rationales provided in response to Clarifax or to justify an approach are not comprehensive
- Discussion of the clinical development plan does not contain enough detail
- The link between the lots used in the clinical trials and the stages of process development is not clear




Recurring Challenges

- Laboratory
  - Sample provision
    - Logistics difficult for small shipments
  - Documents missing
    - Required SOPs/Work Instructions
    - Some details not provided (e.g. sample preparation)
    - CoAs




Recurring Challenges

- OSE Planning
  - Production schedule provision
  - Open discussion of constraints/issues
  - Contractors




Emerging Challenges

180 or 300 days comes very quickly
in an ever changing environment




Emerging Challenges

- Products are becoming more complex
  - Combination products (medical devices, pharmaceuticals)
  - Several Drug Substances are used to manufacture a Drug Product
  - Different strengths and formulations




Emerging Challenges

Manufacturing sites more complex

- Multiple facilities used to manufacture DS and DP
- Different facilities used during development
- Increased use of Contract Manufacturers




Emerging Challenges

- Product development cycle is shortening
  - Late development changes are more common but may not be supported by adequate data
  - Validation at commercial scale not complete
  - Method validation completed but not adequate for intended use




Emerging Challenges

Product ownership is becoming more complex

- Drug Substance manufactured by one company is supplied to another to manufacture Drug Product
- Sponsors vary with marketing area/ product




Thank you to…

My colleagues in CERB and CBE who validated and added to the current and emerging review challenges we face in BGTD




Questions or Comments?…