Yearly Biologic Product Report…

The YBPR and you

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Thank you to…

- Those of you tasked with preparing and submitting the first flight of YBPRs

- My colleagues in CERB, CBE, and CPRA for discussions and comments during the year that have helped shape this talk




Lot Release Program for Schedule D (Biologic) Drugs

- Long standing draft Guidance was revised and finalized in June, 2005
- Guidance outlines the Program and the review and testing requirements prior to release of lots for sale in Canada




Lot Release Program for Schedule D (Biologic) Drugs (con't)

- 4 Lot Release Evaluation Groups
  - Pre-Approval
    - Group 1A: CTA products (usually vaccines)
    - Group 1B: Consistency lots (NDS, S/NDS, DIN-B)
  - Post-Approval
    - Group 2: Lot testing and protocol review
    - Group 3: Protocol review and periodic testing
    - Group 4: Fax notification to BGTD and periodic testing




Lot Release Program for Schedule D (Biologic) Drugs (con't)

- 3 of the key revisions to the Guidance
  - Fax notification for Group 4 products
  - Provision of YBPR (Yearly Biologic Product Report)
  - Increased level of detail regarding the Annual Product Report elements




Why do we need a YBPR?

The YBPR is part of BGTD's life-cycle approach to the regulation of biologics. YBPR review allows BGTD to:

- Assess the on-going safety, quality, and manufacturing control of biologics approved for sale in Canada
- Assess the appropriateness of the Lot Release Evaluation Group
- Determine if periodic testing is warranted

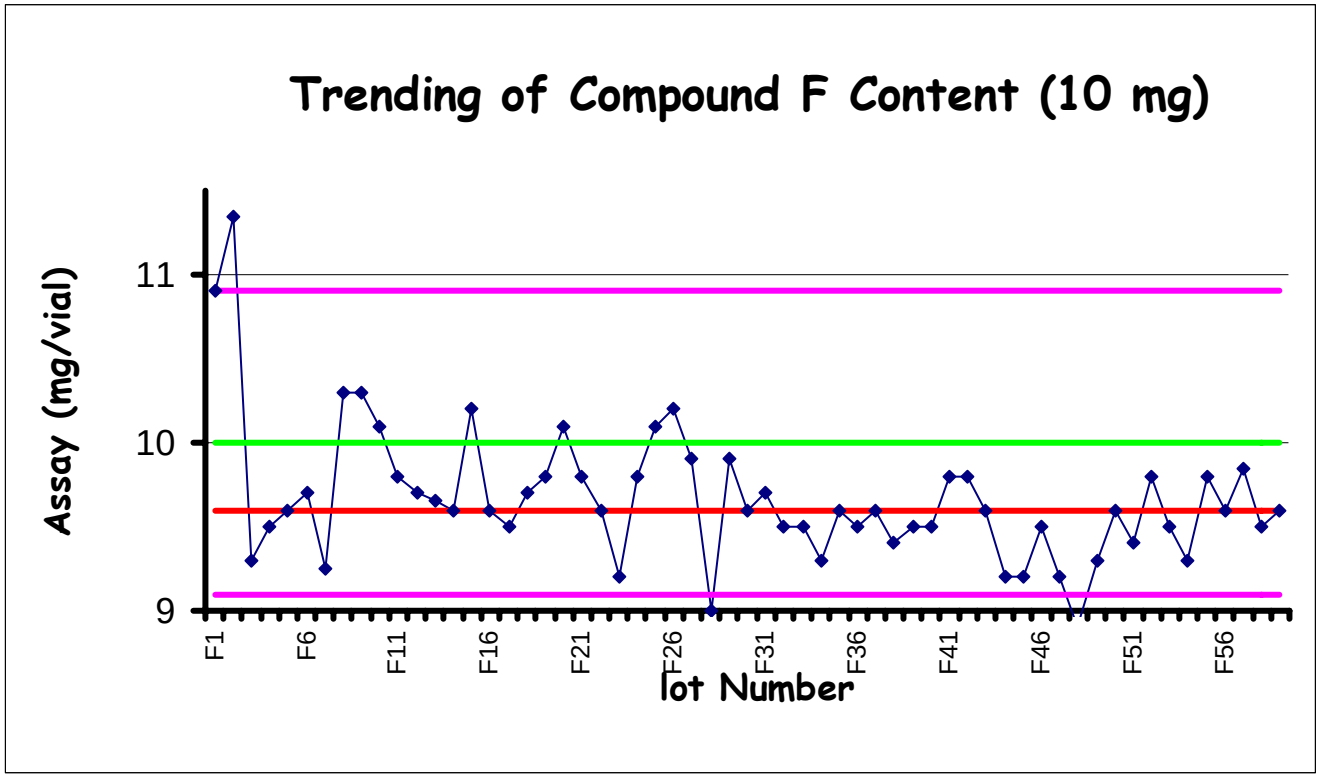



Why do we need a YBPR? (con't)

- The YBPR is beginning to be used as a tool to provide post-market Quality information to BGTD in a formal manner
  - Monitor Progress on commitments: e.g. 'Tighten specifications as manufacturing experience is gained'
  - Monitor potential issues: e.g. different % moisture trends at different facilities
- The YBPR is also an opportunity for the Canadian regulatory affairs staff to evaluate the lots available to Canada in the context of all the lots produced at a facility




Ongoing Product Quality






Ongoing Process Consistency

Lot #	Disposition	Lot #	Disposition
1	Released (NDS lot)	10	Released
2	Released (NDS lot)	11	**Failed** – Aggregates high
3	Released (NDS lot)	12	**Aborted** – low yield in Pur'n
4	Released	13	Released
5	**Failed** - Aggregates high	14	Released
6	**Aborted** – Cell culture; yield	15	**Failed** – Aggregates high
7	Released	16	Released
8	**Failed** – Aggregates high	17	Released
9	Released	18	Retest Aggregates - pending




YBPR format

- Three options to consider:
  - Modify an existing annual report prepared for the FDA or EMEA to reflect the Canadian approval status
  - Prepare a Canadian-specific YBPR using the sections and bulleted points in Section 5.1.1 of the Guidance for format and content
  - Prepare a multi-product YBPR…similar products may be grouped with BGTD agreement




Common Issues with YBPRs

Section 5.1.1.1

- The review aspect of the critical deviations or non-conformances is generally **a summary of the deviations rather than a review.** It should include analysis of the deviations, corrective actions (specific and global), etc.

Section 5.1.1.2

- Frequency of retesting and of invalid tests is not provided or, if provided, they are not compared to previous years




Common Issues with YBPRs (con't)

Section 5.1.1.3

- The review of the critical IPC and the finished product results, as well as the trend analysis for stability-indicating methods should include **all the lots manufactured in a facility**, not just those released in Canada

- A review of the data from **all lots enrolled in the ongoing stability program** should be provided.




Common Issues with YBPRs (con't)

Section 5.1.1.4

- Information on non-Canadian approved facilities (and the lots made there) is not clearly identified

Section 5.1.1.7

- It has been challenging to file the CPID for products with ongoing regulatory activity
  - Provide the last approved CPID for the period under review (include the control number) and a note that states that this is not the most recently approved version




When to File a YBPR

- The filing date is flexible
  - Either no later than October of each year as an Addendum to the Annual Drug Notification Report OR…
  - At an agreed upon time during the year (e.g. to allow coordination with other reporting dates)
    - Contact the appropriate Regulatory Affairs Division to determine the best time to file




Some Questions for you…

- Is a Canadian-specific template needed?
- If yes, is a guidance for completing such a template needed?




Some Questions for me?…