# Establishment Licence Update

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Canada

# Outline

- Highlights
- Annual Licence Review Process
- Challenges and Room for Improvement
- Transformation
- Questions

# Highlights

- API Regulations / Implementation
- Increased focus on “customer service” – implemented standards for response times and quality of the response to inquiries received in generic email / phone accounts
- Significant clean-up efforts undertaken to increase performance / address workload
- Transformed Annual Licence Renewal Process – increased response rates and processing performance – 1 non-responder for DELs and 53 for MDELs – applications processed in 35 days (average)
- HPFBI and TPD GMP initiative

# Annual Licence Review Process

- The Annual Licence Review (ALR) process was a 13 month project – started in December 2012 but not completed until January 2014
- >30 % of DEL applications exceeded the 250 performance standards, even though the standards were being met on average (185 days)
- Lack of service - frequent complaints received– email / voice message boxes were often full - no or delayed response to emails / phone calls
- Issues with non-compliance: 60+ DELs were cancelled as a result of the 2013 ALR process
- Only 50% of ALR packages received were accompanied by a payment - significant number of industry won't pay without an invoice

# Annual Licence Review Process

- ALR process was managed by a dedicated project team
- Streamlined ALR process based on the DIN Annual Notification and Medical Device Licence renewal models
- “Amendments” with ALR (on-site inspections / desk-top evaluation of GMP evidence) no longer permitted
- Elimination of issuing a “new” licence each year
- ALR completed in 35 days on average - anticipate not exceeding the performance standard (250 days) for any DEL

# Challenges and Areas for Improvement

- Challenges:
  - Significant challenges in workload remain
  - Implementation of API regulations
  - Launch of eCES
  - Roll out of new Blood Regulations
- Areas for Improvement
  - Workload Management
  - Risk-based approach to workload – type and source of GMP evidence / DEL application
  - Eliminating waste / non-value added steps / introducing efficiencies in current processes
  - Increase communication / customer-centric approach

# Transformation

- "…..with the objective of streamlining and improving business processes and overall operational performance, the Inspectorate intends to transform various EL processes this year. Specifically, the Inspectorate will develop separate and distinct business streams for the following EL processes:
  - Applications for a "new" EL
  - Applications to "amend" or to provide "notifications" for an existing EL
  - Applications for "annual review"

- "Not all GMP evidence is created equal"…..will initially develop and "express" lane for MRA/CoC evidence

- Will be exploring other lanes for evidence coming from "respected / trusted" regulatory authorities including FDA, MRA partners in non-MRA countries, PICS members

# Questions

Questions?