TAT 11 Symposium
Clinical Day - Session III (April 4, 2019)
Regulatory Aspects of Alpha Therapy in Patients

Patrick S. Ruddock, M.Sc.
Manager, Regulatory Affairs
Centre for Probe Development and Commercialization
Disclosures

I (Patrick Ruddock)

- An am employee of Centre for Probe Development and Commercialization (CPDC), a non-profit pharmaceutical company
- Own stock in Fusion Pharmaceuticals Inc., a pharmaceutical company and sponsor of the TAT 11 symposium
My background

- M.Sc. (Microbiology), U of Ottawa
- Post-graduate Regulatory Affairs program, Humber College, Toronto
- 10 years experience in regulatory field
  - Worked at CPDC since 2011
  - Previously worked for Baxter International (medical devices and biologics)
  - Commercial and investigational product submissions to Health Canada and FDA, including diagnostic and therapeutic radiopharmaceuticals
CPDC background

Not-for-profit radiopharmaceutical (RP) company headquartered in Hamilton, Ontario
• Facilities in Hamilton, Toronto, Ottawa and Boston

CPDC products
• Commercial (F-18): FDG (CAN & US) & NaF (CAN)
• Investigational (F-18): DCFPyL, FAZA, FCH, FLT (CAN)
• Investigational: [Ga-68]- and [Lu-177]-DOTATATE (CAN)

Contract manufacturing for [F-18], [In-111], [I-123], [I-124], [I-131], [Lu-177], [Ac-225] & [Tc-99m]-based RPs

Regulatory consulting and support for pharmaceutical companies and local researchers
Info needed for CTA/IND

- **Quality ("CMC")**
  - Quality of critical starting materials & other ingredients/reagents/excipients
  - Validated manufacturing process & shelf-life
  - Approved specifications & QC tests
  - Characterisation of drug substance & impurities

- **Non-clinical**
  - Evidence of target binding & (if applicable) therapeutic effect
  - PK, biodistribution and dosimetry
  - Toxicity

- **Clinical**
  - Clinical trial protocol and informed consent form
  - Investigator’s Brochure
What does Regulatory Affairs do?

Make the regulator’s task reviewing/clearing your application easy: provide the required quality, safety and efficacy information, in the correct format, with accurate summaries, interpretation, context and justifications

• Prepare and submit CTAs/INDs
• Liaise with regulators
• Work with QA, QC, production, process & analytical development, clinical & investigators to move products into/thru clinical trials
• Provide input on CMC & clinical development plans; review data
• Review clinical trial protocols, informed consent forms, and IBs
• Review and approve labels for regulatory compliance
• Post-clearance, assess changes to determine reportability, is regulator clearance needed & supporting info
• Monitor changes to regulatory environment