BREAKING INTO THE BIOTECH INDUSTRY– INSIGHTS FOR SMOOTH SAILING

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Disclaimer: The views and opinions expressed in this presentation are those of the author and do not necessarily reflect the official policy or position of Axovant Sciences.
PhD Toxicology, UNC Chapel Hill
Thesis: Mechanisms of DNA damage, repair and genome maintenance in orphan disease and cancer

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EDUCATION (GRADUATE): AT A GLANCE

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Preparing for the next step: Industry Postdoc (Pharma and Biotech)
- Continuing Education (seminar series)
- Networking
- Internship

Defense
In retrospect: what I would have done differently
• take advantage of university resources
• More courses on science in industry
• Regulatory guidance documents
• Networking/ interning earlier

What I think most contributed to my hiring:
• Communication skills (oral, written)
• Awards, grants, publications
• Project handling (including maintaining collaborations) & adaptability
• Networking & internship
THE HIRING PROCESS

**Current Job:**
- Networking (have a general goal in mind)
- Internship
- Cover Letter/ Resume/ LinkedIn
- Onsite Interview
- Offer

**General:**
- Preparation for going on the job market:
  - Cover Letter
  - CV/Resume
  - LinkedIn
  - Do your research!
- Networking/ Recruiters
- Phone Interview (recruiter \(\rightarrow\) HR \(\rightarrow\) hiring manager)
- Onsite Interview
- Offer
- Negotiation
- Acceptance
CURRENT ROLE

Postdoctoral Fellow, Nonclinical Drug Development

- DILIGENCE/ DISCOVERY
  - 5,000-10,000 compounds
  - $5,000-$10,000

- PRECLINICAL/ IND- ENABLING STUDIES
  - 250
  - $$

- CLINICAL TRIALS
  - Phase I
    - 5
    - $$
  - Phase II
    - $$
  - Phase III
    - $$$

- FDA REVIEW
  - IND Submission
  - NDA Submission
  - Approval

1 Approved product

10-15 years

A thorough early development program de-risks high cost, late stage development
NONCLINICAL ROLE IN DRUG DEVELOPMENT

- Due diligence reviews of compounds for in-licensing or acquisition
- Nonclinical bioanalysis
- Pharmacology/efficacy/ MoA
- Pharmacokinetics/ allometry
- ADME/ radio-labeled studies
- General Toxicology
- Drug metabolism/ disposition
- Regulatory document support

- Clinical & nonclinical bioanalysis
- Environmental risk assessment
- Reproductive toxicology
- Genetic toxicology/ carcinogenicity
- In vitro DDI analysis
- Abuse liability
- Safety & secondary pharmacology
- Regulatory document support
- Communication strategy and publication preparation

- Regulatory document support
- Support for phase IV studies
- Collaboration with Med Affairs on market differentiation in competitive landscape

New Indication Validation
PRECLINICAL APPROACHES TO GENE THERAPY

A new field with lots of uncharted territory

- Design of vector
- Selection of preclinical species
- Pharmacology (Dose-Response, MoA)
- Safety studies uniquely catered to product
- Bioanalysis, Biodistribution & Shedding
- Long-term efficacy & limits on future use
DAY-TO-DAY CONTRIBUTIONS

- Overseeing the development of bioanalytical methods and in-life studies (e.g. Pivotal IND and registration-enabling)
  - Design, on-site monitoring and data analysis and reporting
  - Bioanalytical, pharmacology and toxicology studies
  - Operational oversight (contracts, invoicing, project management, vendor relations)
- Regulatory contributions (E.g. Annual Reports, IB, IND)
- CMC
  - Device compatibility testing
  - Bioanalysis and release testing
  - Potency assay development
- Translational/ Clinical
  - Identifying and sourcing KOLs
  - Developing bioanalytical methods for clinical monitoring and endpoints
  - Design nonclinical studies in support of clinical study design
- Business Development
  - Due diligences
  - New indications
WHAT I LOOK FOR IN JOB CANDIDATES

• Adaptability and work ethic

• Team work and interpersonal skills
  o How do they deal with conflict/ challenges?

• Leadership/ responsibility

• Communication
  o Resume- well laid out? Free of errors?
  o Answers questions succinctly and directly?

• Problem solving
  o How do they approach questions/ deal with unknowns?

• Education, Experience, Qualifications
  o Degree, background
  o Certifications?
  o Technical expertise?
Thank you.