



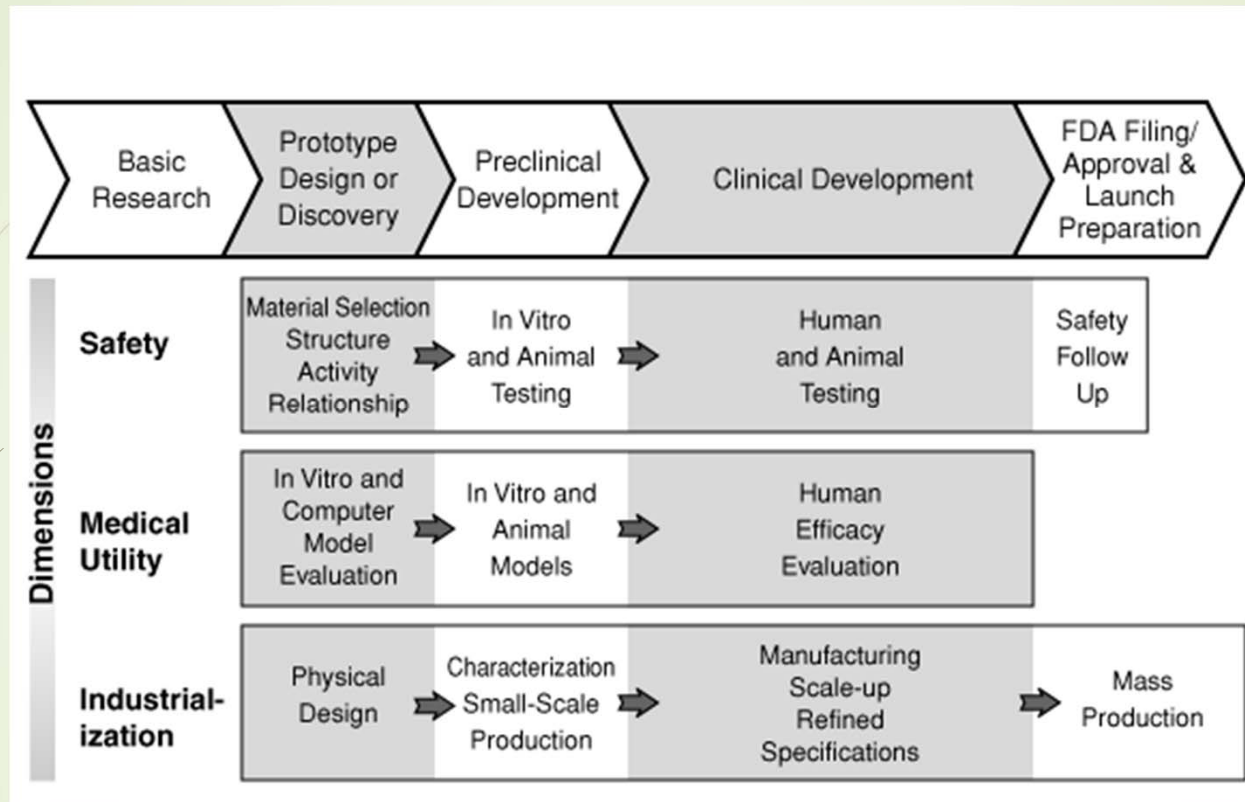
“From Bench To Clinic”: a personal journey Career Research Advancement Focused Training

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Vice President of Translational Medicine

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FDA view of medicinal product development

Activities to support drug development

Assessing Safety

Definition

Show that product is adequately safe for each stage of development

Examples of Activities

- Preclinical: show that product is safe enough for early human testing
- Eliminate products with safety problems early
- Clinical: show that product is safe enough for commercial distribution

Demonstrating Medical Utility

Show that the product benefits people

- Preclinical: Select appropriate design (devices) or candidate (drugs) with high probability of effectiveness
- Clinical: show effectiveness in people

Industrialization

Go from lab concept or prototype to a manufacturable product


- Design a high-quality product
 - Physical design
 - Characterization
 - Specifications
- Develop mass production capacity
 - Manufacturing scale-up
 - Quality control



Training

- ▶ Kazan Federal University, Russia: Undergraduate degree in Microbiology. Entered Graduate program in Biochemistry
- ▶ Albert Einstein College of Medicine, NY USA: Molecular Pharmacology Master of Science and Ph.D Degree
- ▶ Duke University, NC USA: Post doctoral fellowship in a field of Nuclear Hormone Receptors (breast cancer)
- ▶ Selected a small Biotech company to have ability to interact with wide range of professions

Interested in development drugs for human health management



My interest is applied and translational science

- ▶ Interested in becoming scientific leader
 - ▶ non scientific training
 - ▶ Psychology course at Kazan Federal University
 - ▶ Leadership workshop at Duke University
 - ▶ Scientific writing course (2 semesters) taught by English language professor (post Ph.D. degree)
 - ▶ Training for managers organized by Company
- ▶ Wanted to know more outside of science discipline
 - ▶ Organized similar seminars to learn about non traditional careers during post doc tenure

Drugs in pipeline

In license combined
with internal R&D

**Recombinant protein CD83
for autoimmune diseases**

In license from Baylor University
Pre clinical development with Novo Nordisk

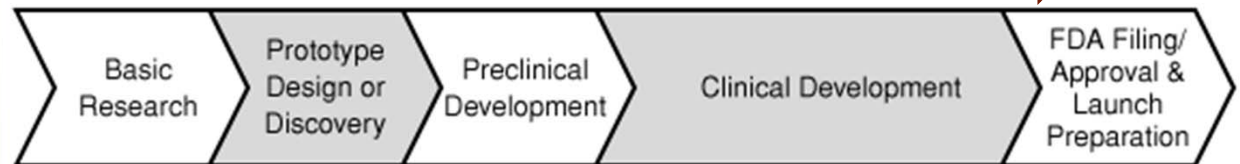
**Antibodies for
autoim disease**

Internal invention

Anti HIV cellular vaccine

In license from Duke University

Cancer cellular vaccine





Carrier development on a job

- ▶ Senior Scientist Molecular Biology
 - ▶ Design and execute experiments. Write reports. Publish research in peer reviewed journals. Technology transfer from University laboratories
- ▶ Group leader
 - ▶ Coordinate work of several employees. Make hiring decisions
- ▶ Manager Molecular Biology Research and Early Development
 - ▶ Responsible for delivering of results by entire group. Train employees. Make hiring and firing decisions. Contribute to sections of regulatory filings. Project management. Assure reduction to practice of an invention for patent



Carrier development on a job

► Director Molecular Biology

- Understand the goal of the project and design experimental program that will deliver the result. Responsible for building a team, motivating employees and retaining talent. Coach employees on project management and managing other employees. Responsible for assuring funding for some programs. Identify external resources required for achieving goals. Compose RFPs, manage work of external laboratories. Foster productive collaborations with Academic laboratories. Contribute to regulatory filings. Manage resources, compose budgets. Peer review of manuscripts

► Sr. Director Research and Development

- Assess gaps existing in order to achieve desired goal. Thorough understanding of regulatory requirements. Leading technology transfer to corporate partners. Assure seamless work of R&D department with other departments in Company.



Carrier development on a job

- ▶ Vice President of Translational medicine
 - ▶ Evaluation of competitive landscape
 - ▶ Evaluation of business and in-license opportunities and other business opportunities. Due diligence
 - ▶ Translation: understanding the deliverable required by other department (QA, Regulatory) and structure work to achieve the established goal
 - ▶ Contributing to strategic development of company



Potential future positions

- ▶ Chief Scientific Officer
 - ▶ President of a Company
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Other career paths available

- Regulatory department
- Quality assurance department
- Quality control department
- Intellectual property management
- Business development
- Project management
- Product development/manufacturing operations