Career Growth Areas in Physiology / Pharmacology

Magdalena Alonso-Galicia, PhD
Pharmacology Department
Forest Research Institute, Inc.
Jersey City, NJ
Career Growth Areas in BioPharma

- **Pharmaceutical & Biotech companies:**
  - Chemistry-based “small molecule” products
  - Biologics such as therapeutic proteins, antibodies, RNA & DNA

<table>
<thead>
<tr>
<th>Drug Discovery &amp; Development</th>
<th>Biotechnology Tools &amp; Services</th>
<th>Other BioPharma areas</th>
<th>Governmental Institutes</th>
<th>Medical Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharma</td>
<td>Reagents &amp; Chemical Supplies</td>
<td>Molecular Diagnostics</td>
<td>FDA</td>
<td>Diagnostics</td>
</tr>
<tr>
<td>Biotech</td>
<td>Platform companies</td>
<td>Veterinary Products</td>
<td>CDC</td>
<td>eHealth</td>
</tr>
<tr>
<td>Vaccines</td>
<td>Software companies</td>
<td>Non-profit institutions</td>
<td>NIH</td>
<td></td>
</tr>
<tr>
<td></td>
<td>CRO &amp; CMO</td>
<td>Academia-Industry Collaborations</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>VC Firms</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Changing Landscape in Drug Discovery & Development

The traditional drug development process helped to increase life expectancy and reduce morbidity in very large population groups suffering from a wide variety of diseases and illnesses.

- Thousands of in-house scientists in biopharma helped to develop drug candidates from scratch at a very high cost.

- This business model was successful up until ~2001.

- However, numerous layoffs in R&D teams at drug developers and especially in big pharma have occurred in recent years.
Changing Landscape in Drug Discovery & Development

- **Contributing factors:**
  - Increased competition from generic drugs: Many blockbuster branded medicines are losing patent protection.
  - Decline in R&D productivity.
  - Unprecedented pressure on drug pricing.
  - More strict regulatory standards for drug approval & promotional activities.

- **Moving forward, the pharmaceutical industry will need to:**
  - Reverse the decline in R&D productivity: Innovative partnerships.
  - Improve success rates for regulatory approval: Streamline development phase.
  - Deliver differentiated medicines that add incremental value to the current standard of care.
Career Growth Areas in Drug Development

Discovery Research:
- Target ID
- Target Validation
- Lead ID
- Lead Optimization

Ph 0 Exp Medicine (EM)

Preclinical Research:
- Safety Pharmacology
- Toxicology
- Nonclinical PK and ADME
- Bio / Chemical Process Development

IND Filing, EM

Clinical Development & Regulatory Affairs:
- Clinical Trials: Phase I, II, IIIA
- Drug Scale-Up & Manufacturing
- NDA Filing
- FDA Review
- Product Launch

Specialized markets / therapeutic areas

Medical Affairs:
- Commercial Operations and Sales
- Clinical trials: Phase IIIB, IV
- Technical support

Licensing & business development activities

Big/small bio/pharma, academia

In-house or CRO

Need integrative physiologists / pharmacologists with knowledge in multiple therapeutic areas.
Discovery Research – The Idea Makers

- Discovery Research will be conducted mostly at specialty pharma/biotech, academia

- Most physiologists / pharmacologists start out at the bench. Recruitment is based on:
  - Scientific expertise relevant to human disease / targets
  - Excellent publishing record
  - Post-doc research was different from graduate work
  - Excellent professional presentation skills
  - Candidate is enthusiastic, a team player with a “can do” attitude
Discovery Research - Management Track

- Manage and lead PhD and/or junior scientists in a particular therapeutic area or discipline:
  - Scientific oversight: Picking & managing the most promising projects
  - Recruiting and building teams of motivated, highly productive scientists
  - Effective resource allocation
  - Staff management & performance
  - Embrace lifelong learning and have a flexible attitude
Discovery Research Career Potential

- Launching platform for just about any career direction in Pharmaceutical & Biotech companies, CROs, etc.
Clinical Development & Operations

- Current demand for clinical professionals is very high and is expected to grow in the future.
  - Experience in clinical development is a must.
  - Opportunities to break into the clinical field via CROs and FDA positions, and postdoctoral fellowships in clinical research.

- Career potential for physiologists / pharmacologists:
  - Preclinical & Clinical Pharmacology
  - Medical Writing
  - Translational Medicine – Intersection of discovery research and clinical development
  - Clinical team & program leaders: Scientific and strategic responsibilities.
Regulatory Affairs

- Excellent career with great potential for physiologists / pharmacologists with drug discovery & development experience.

- Specialized expertise that is very marketable
- Demand for regulatory affairs professionals is predicted to increase because the industry is becoming even more regulated
- Requires a deep understanding of every step of drug development from beginning to end.
  - Having a strong science background is essential.
Business Development / Licensing

- Pharmaceutical companies will license more drug candidates that are ready to enter clinical trials.

- Career growth areas for physiologists / pharmacologists:
  - Competitive intelligence
  - Portfolio management
  - Technology and products scouts

- Experience is one of the keys to success in business development
  - Requires excellent interpersonal & diplomatic skills
  - Broad knowledge of the industry (science, legal, development)
Suggestions

- Emphasis on integrative physiology / pharmacology programs:
  - Expertise in multiple therapeutic areas desirable
  - Interdisciplinary exposure (toxicology, clinical research, etc.)

- Early career coaching:
  - Leadership, management skills
  - Personal career goals & expectations
  - Work/life balance

- Exposure to all aspects of drug discovery & development
  - Big/small companies
  - Academia
  - CROs