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MAKING AN IMPACT BEYOND ACADEMIA

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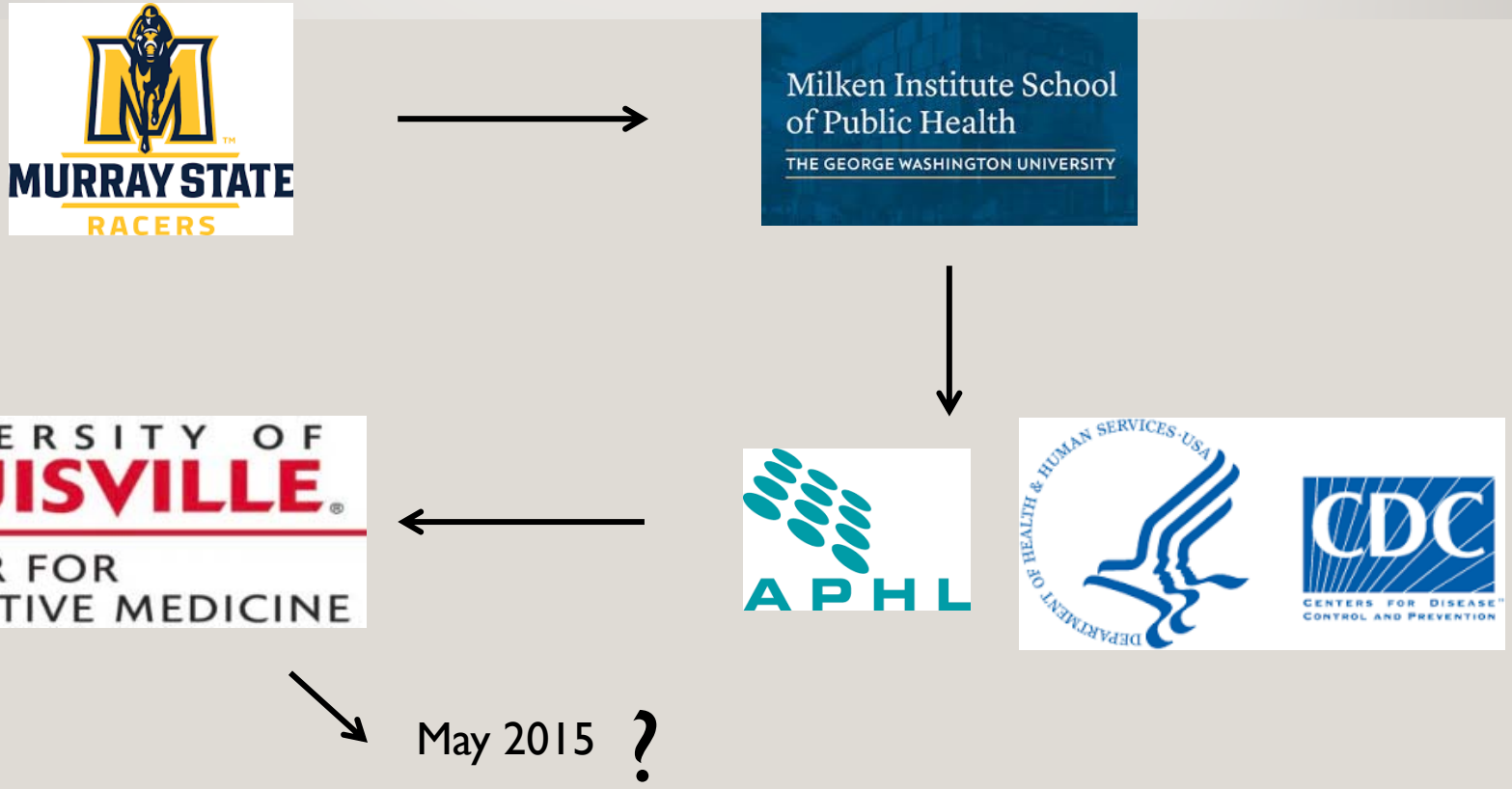
DISCLOSURE

- The content of these slides and opinions expressed reflect my personal opinion and may not reflect the opinions of US WorldMeds, LLC

OUTLINE

- My Path to Industry
- What I've Learned Along the Way
- Opportunities for Life Scientists in the Pharmaceutical Industry
- Who is US WorldMeds

MY BACKGROUND- PATH TO INDUSTRY



DECISION TO MOVE INTO INDUSTRY

BENEFITS

Public Health
Prevent. Promote. Protect.

Day to Day Challenges

I WISH I KNEW THEN WHAT I KNOW NOW

7 TRANSFERRABLE JOB SKILLS

HOW TO ARTICULATE THOSE SKILLS IN A "VALUE PROPOSITION" TO AN EMPLOYER

1. Analysis and Problem Solving
2. Interpersonal and Leadership
3. Project Management and Organization
4. Research and Information Management
5. Self Management and Work Habits
6. Written and Oral Communication
7. Subject Matter Expertise- this extends farther than you think?

#1 ANALYSIS AND PROBLEM SOLVING

- Ability to define a problem and identify possible causes/solutions
- Comprehend large amounts of information
- Form and defend independent conclusions
- Design an experiment, plan, or model that defines a problem, tests potential resolutions and implements a solution

#2 INTERPERSONAL AND LEADERSHIP

- Facilitate group discussions or conduct meetings
- Motivate others to complete projects (group or individual)
- Respond appropriately to positive or negative feedback
- Collaborate on projects and well on a team (your lab, your department or center) as well as cross-functionally (in collaboration within your group or with other groups)

#2 INTERPERSONAL AND LEADERSHIP

- Effectively mentor and coach young scientists and/or peers
- Teach skills or concepts to others (classroom, one-on-one)
- Influencing and negotiating skills (from writing funding bids, securing resources from within your dept etc)

#3 PROJECT MANAGEMENT AND ORGANIZATION

- Manage a project or projects from beginning to end (dissertation research, lab got new instrument)
- Identify goals and/or tasks to be accomplished and a realistic timeline for completion
- Prioritize tasks while anticipating potential problems
- Maintain flexibility in the face of changing circumstances
- Put together a budget (grant application)
- Line Management (recruiting, developing, motivating, and assessing performance)
- Financial and resource management

#4 RESEARCH AND INFORMATION MANAGEMENT

- Identify sources of information applicable to a given problem
- Understand and can prioritize large quantities of data
- Develop organizing principles to effectively sort and evaluate data

#5 SELF-MANAGEMENT AND WORK HABITS

- Work effectively under pressure and to meet deadlines
- Comprehend new material and subject matter quickly- (i.e. journal clubs)
- Work effectively with limited supervision

#6 WRITTEN AND ORAL COMMUNICATION

- Prepare concise and logically-written materials
- Designing, preparing and delivering ideas (in lectures)
- Organize and communicate ideas effectively in oral presentations to small and large groups (conferences, journal clubs, etc.)
- Write at all levels — brief abstract to book-length manuscript/dissertation to grant applications- communicating significance and limitations
- Debate issues in a collegial manner and participate in group discussions
- Explain complex or difficult concepts in basic terms and language

#7 SUBJECT MATTER EXPERT

- Flow cytometry, cell culture, western blotting, cloning, PCR, using various isolation kits, animal models, serology, etc.
- Research area: can be as broad as microbiology or biochemistry

Where Can I Fit?

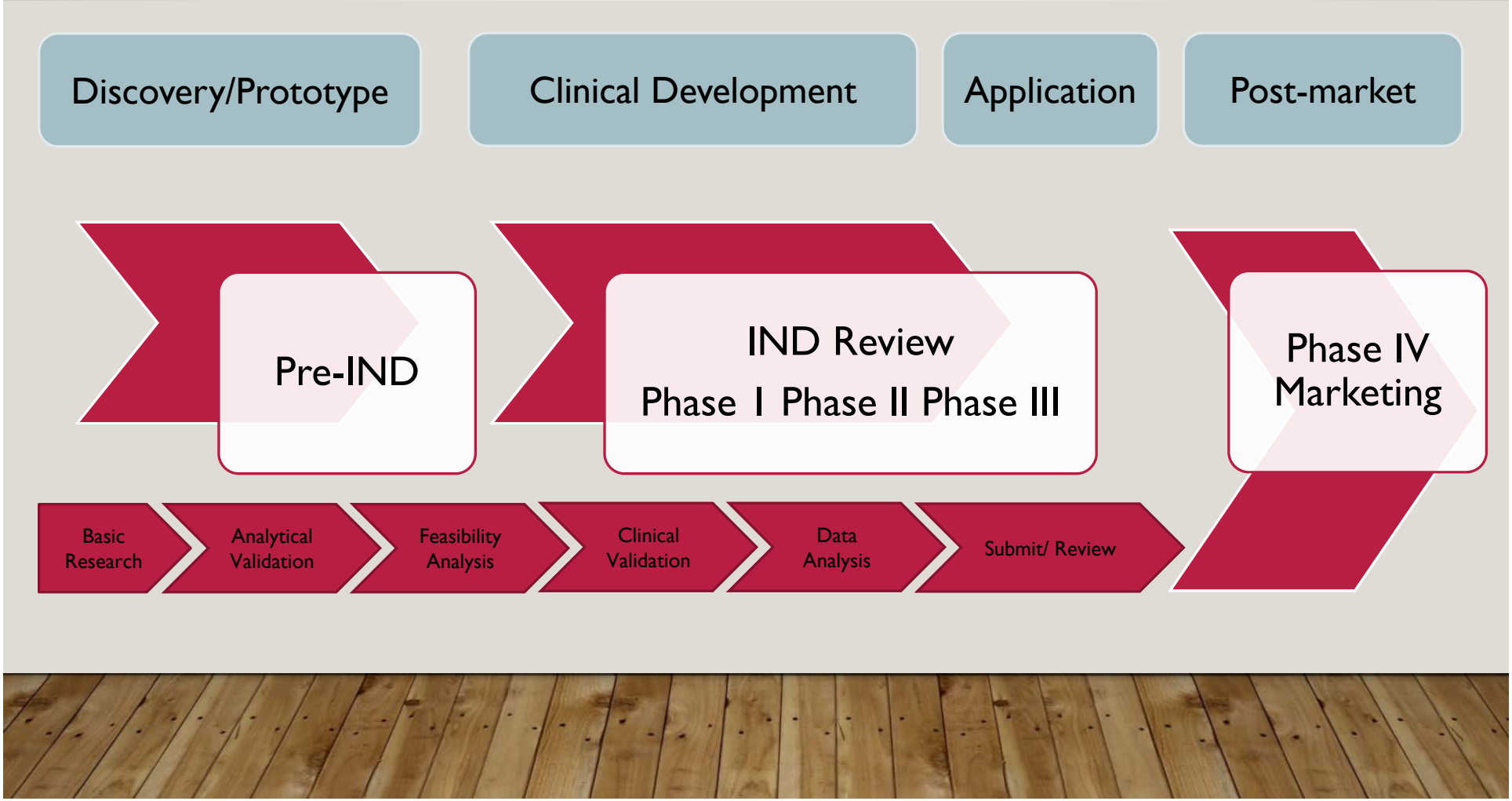
IF YOU DON'T KNOW- START SMALL

- Look for small-medium size company
- Ability to join different cross-functional projects
- Ability to learn about the different areas of the company
- Ability to learn where you provide value most

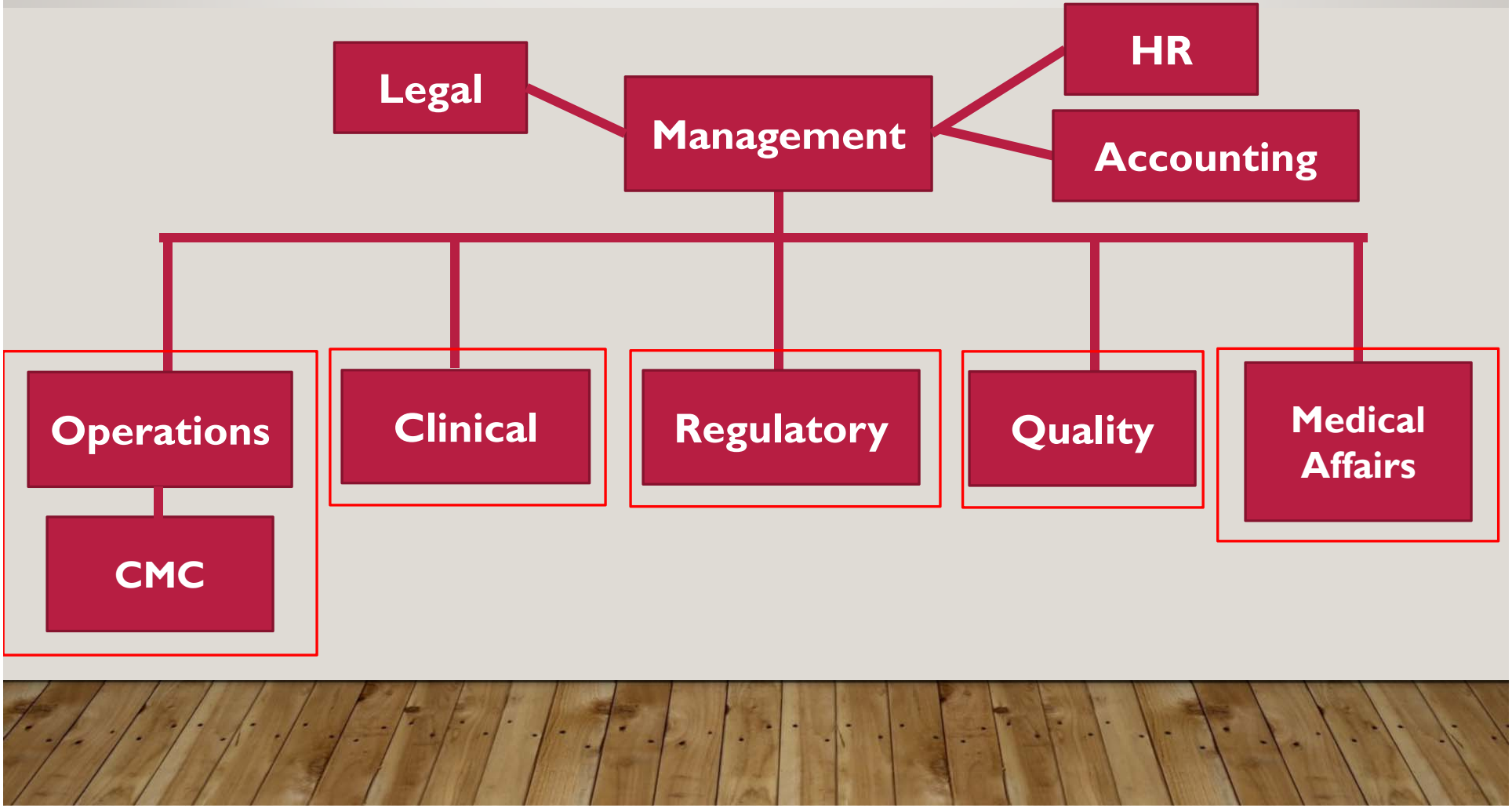
ROLE OF PHARMACEUTICAL COMPANY

- Pharmaceutical companies are responsible for the discovery, testing, manufacturing, and marketing of products that are safe and make a worthwhile contribution to public health

DRUG DEVELOPMENT PATHWAY



PHARMACEUTICAL COMPANY STRUCTURE



CMC- CHEMISTRY, MANUFACTURING AND CONTROLS

- Roles: Development Scientist, Formulation Scientist, Manager, Director
- Responsibilities: Collaborates closely with multiple departments – scientific, regulatory, quality, and operations – within the company and drives external activities at contract manufacturing and contract laboratory organizations (CMOs and CROs, respectively)
  - Responsible for pre-clinical study and design
  - Determine appropriate formulation and manufacturing process conditions that result in a drug product with acceptable physicochemical properties.
  - Establish product shelf life and validate a process for drug product identity, quality, purity and potency
  - Ensure drug is manufactured according to cGMP requirements and manage lifecycle of drug product (i.e, new formulations)
  - Contribute to marketing applications
- Skills: strong chemistry and analytical background, familiarity with manufacturing process optimization and cGMP principles, knowledge of appropriate regulatory requirements, scientific rigor, troubleshooting, and analysis

QUALITY MANAGEMENT

- Role: QA Lead, Analyst, or Engineer, Manager, Director
- Responsibilities: Ensure drug manufacturers are cGMP compliant:
  - their personnel have appropriate educational and experiential backgrounds
  - equipment is installed, operational and fully maintained
  - complete traceability and proper storage of ingredients, packaging components and products
  - production, process, packaging, labeling and laboratory controls are present
  - documentation (from formulation, through production and testing) is complete and has appropriately dated verification steps.
- Skills: Strong writing skills, detail-oriented

REGULATORY

- Role: Regulatory Associate, Specialist, Scientist, Manager, Director
- Responsibility:
  - Keeping track of the ever-changing legislation in all the regions in which a company wishes to distribute its product
  - Manages interactions with government agencies (FDA, EMA, etc.)
  - Collecting, collating and evaluating scientific data
  - Preparing documentation and registration documents to regulatory agencies and carrying out any subsequent negotiations necessary to obtain or maintain marketing authorization for drug products
  - Give strategic and technical advice, from the beginning of product development- making an important contribution both commercially and scientifically
- Skills: Strong writing and communication skills, critical thinking and strong time/project management skills

CLINICAL OPERATIONS

- Role: Clinical Project Manager, Clinical Trial Associate, Clinical Research Associate, Data Scientist, Programmer, Statistician, Medical Writer, Manager, Director
- Responsibilities:
  - Plan, track and manage the conduct and evaluation of clinical research
  - Drives external activities at contract research organizations (CROs)
  - Develop clinical protocols- interacting with Key Opinion Leaders
  - Collect, process, and analyze clinical data (statistical team)
  - Report clinical results
- Importance: Goal of trials to determine the products potential at benefiting the patients
- Skills: Project management, organization, detail oriented, strong analytical skills, strong written and oral communication

MEDICAL AFFAIRS

- Role: Medical Science Liaison, Manager, Director
- Responsibilities: Collaborates closely with multiple departments within the company and drives external activities
  - Manages key thought-leader relationships
  - Publishes data from corporate-sponsored trials
  - Presents data at scientific and clinical conferences
  - Presents educational information about a product or therapeutic landscape
  - Answers questions from healthcare providers regarding product safety or efficacy that is not addressed in a product's label
  - Supports research initiatives outside labeled indications for marketed products.
- Skills: scientific rigor, ability to communicate effectively both in person and in writing

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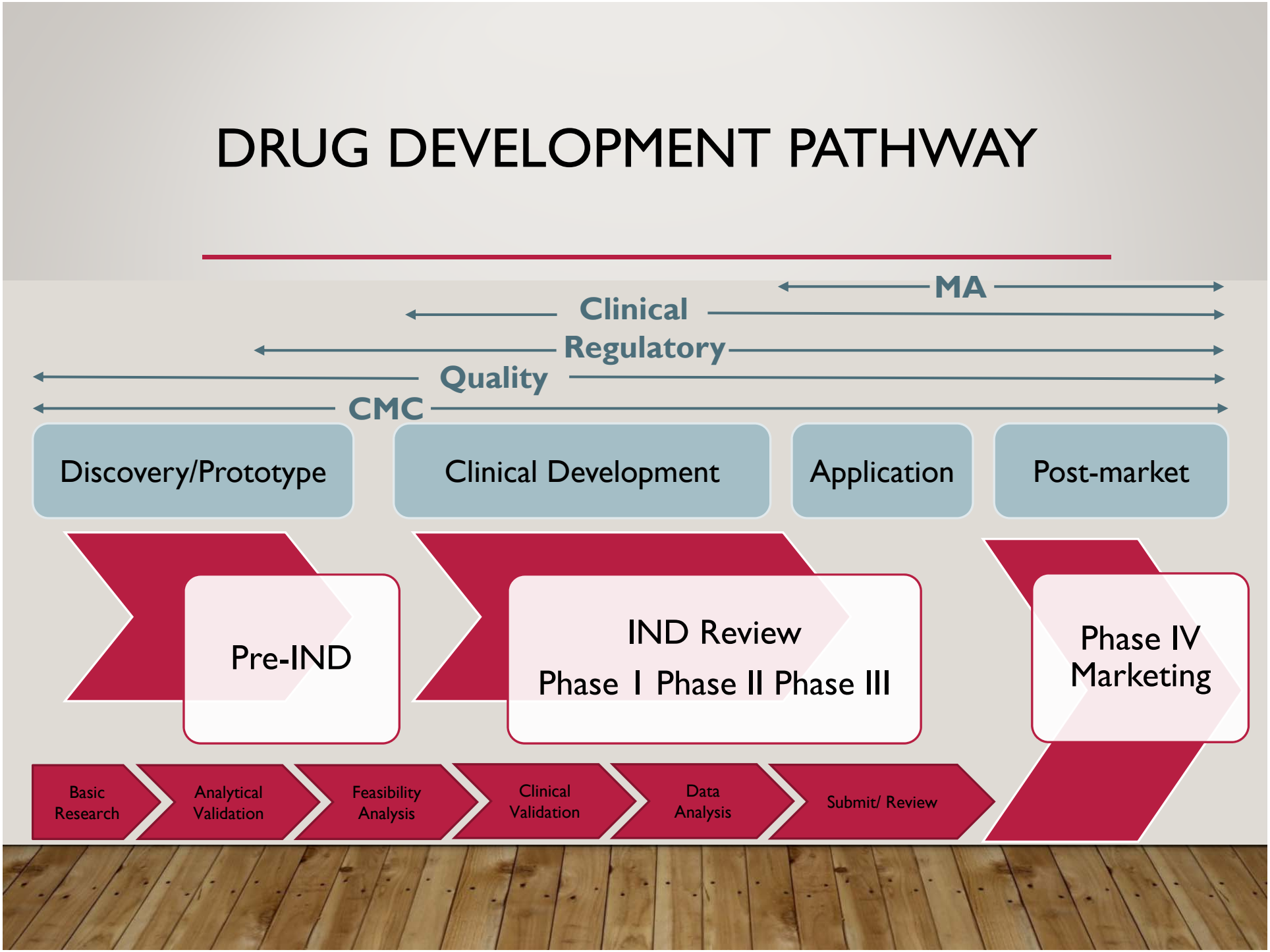

RECOMMENDATIONS

DON'T BE AFRAID TO INTERN

INTERNSHIPS

- Myth: Internships are only for undergrads
- However, there are number of major companies who offer short summer workshops and internships and many Universities that allow graduate researchers to do such internships
- Internships offered by consulting firms, pharmaceutical companies, and intellectual property firms.
- If you do an internship in a non-research role that is aligned with the career you want to pursue, it will allow you to rapidly develop the transferable skills you need to get an industry job.

BENEFITS TO INTERNING- COMPETITIVE EDGE

BUILDING YOUR CV

Academia

- Emphasis on what you have already achieved
- Focus on scientific credibility
- Focus on scientific accomplishments
- List publications, presentations, and conferences

Industry

- Emphasis on how your achievements can be applied
- Focus on skills necessary for job you are applying for
- Short, sharp and to the point
- List teamwork, communications, leadership (management)

HOW TO INTERVIEW

- In an interview situation, be eager, show a desire to learn and be flexible, and ask the questions you want answered
- Highlight your **transferrable skills**
- Think of examples of each
- Give thought to your values and what your career goals are- doesn't have to be a grand view

WHO IS US WorldMeds

MISSION AND VISION

Mission

- We will develop, license and market meaningful and accessible healthcare products that improve lives and result in a thriving community of patients, employees and shareholders

Vision

- We will create a sustainable privately held specialty pharmaceutical company known for our agility and personal attention to our products and stakeholders achieved through our teammates who define us, our shareholders and partners who believe in us, and our patients who inspire us

MARKETED PRODUCTS

APOKYN®
apomorphine hydrochloride injection

Revonto®
(dantrolene sodium for injection)

MYOBLOC®
rimabotulinumtoxinB
Injection [5,000 Units/mL]

Corgard®
(nadolol tablets, USP)

Lucemyra™
(lofexidine) tablets 0.18 mg

XADAGO
(safinamide)

US WorldMeds™

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