UNC aaps®
American Association of Pharmaceutical Scientists

# AAPS SPEAKER EVENT

KBI BIOPHARMA

September 28, 2017

Speaker: Nate Oien, PhD

You may submit questions by clicking the link on AAPS.web.UNC.edu

# UPCOMING EVENTS

- October 20, 2017:
  - Site visit to KBI Biopharma
  - Located in Durham, NC
  - Can carpool, will need to sign up beforehand.
- November Event
  - Speaker event from NC Biotech Center
  - Dr. Laura Rowley
  - Alumni of UNC
- Next Semester…

# NEW CABINET

- President: Maurice Horton (CBMC)
- Vice-President: Steve Yan (CBMC)
- Secretary: Alice Cheng (PharmD)
- Treasurer: Randy Qian (DPMP)

# Prepare for Renewal

| Due date | Renewal Period Closes | Stipends Mailed By |
|---|---|---|
| November 1 | Dec. 15 | Jan. 15 |

- ✓ Confirm that your chapter will have 10 paid members at time of renewal. All officers and FA must by AAPS member!
- ✓ Will be sending out a survey as AAPS requires:
  - Name of AAPS members and non-members
  - AAPS Member ID for paid members
  - Email addresses
  - Mailing addresses
  - Phone number
  - Anticipated graduation year

# Industry Jobs: Biopharmaceutical Employment Opportunities

Nathan P. Oien, Ph.D.

THE SCIENCE TO SUCCEED.

# Biologics, a market outlook

**Table I: Combined global prescription sales for the top 50 pharmaceutical companies (excluding generic-drug companies) by molecule type (2009–2014).**

| | Sales ($ billion) | | | | | | |
|---|---|---|---|---|---|---|---|
| Molecule type | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | Difference in sales between 2009 and 2014 |
| Small molecule | 411 | 414 | 415 | 405 | 394 | 394 | –4% |
| Therapeutic protein | 65 | 68 | 70 | 72 | 74 | 76 | 17% |
| Monoclonal antibody | 38 | 43 | 48 | 53 | 58 | 62 | 63% |
| Vaccine | 21 | 22 | 24 | 25 | 27 | 28 | 33% |

Sources: Datamonitor, PharmaVitae Explorer, January 2010, and company-reported information.

<u>Types of Proteins</u>

-Insulin, Growth Factors, Interferon

-Antibody-Drug Conjugates (ADCs)

-Fusion Proteins

# KBI Biopharma Mission Statement

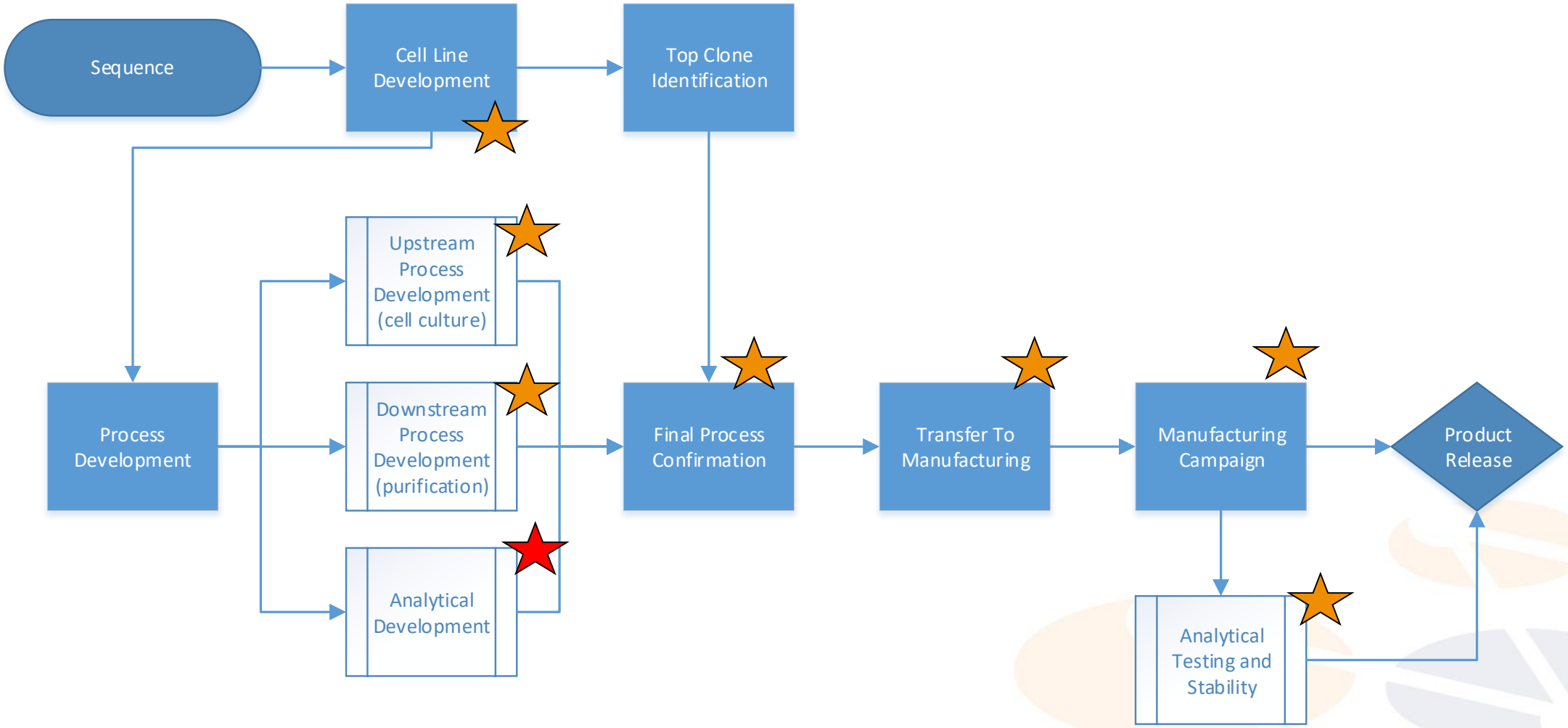
- Our mission is to *accelerate* the development of innovative discoveries into life-changing biological products and expand global access too medicines to patients in need.

| Discovery | Development | Clinical Trials | | | Commercial | Phase IV – Post Market |
|---|---|---|---|---|---|---|
| | Preclinical | Phase 1 | Phase 2 | Phase 3 | | |

KBI

From Sequence to Clinical trials in ????

# Typical KBI Project Life Cycle

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= Opportunities for you

THE SCIENCE TO SUCCEED.

# Additional Opportunities

- Process Characterization
- Process Validation
- Product Characterization (Mass Spec)
- Regulatory
- Formulation Development
- Technical Support and Sales

# Am I Right for Industry?

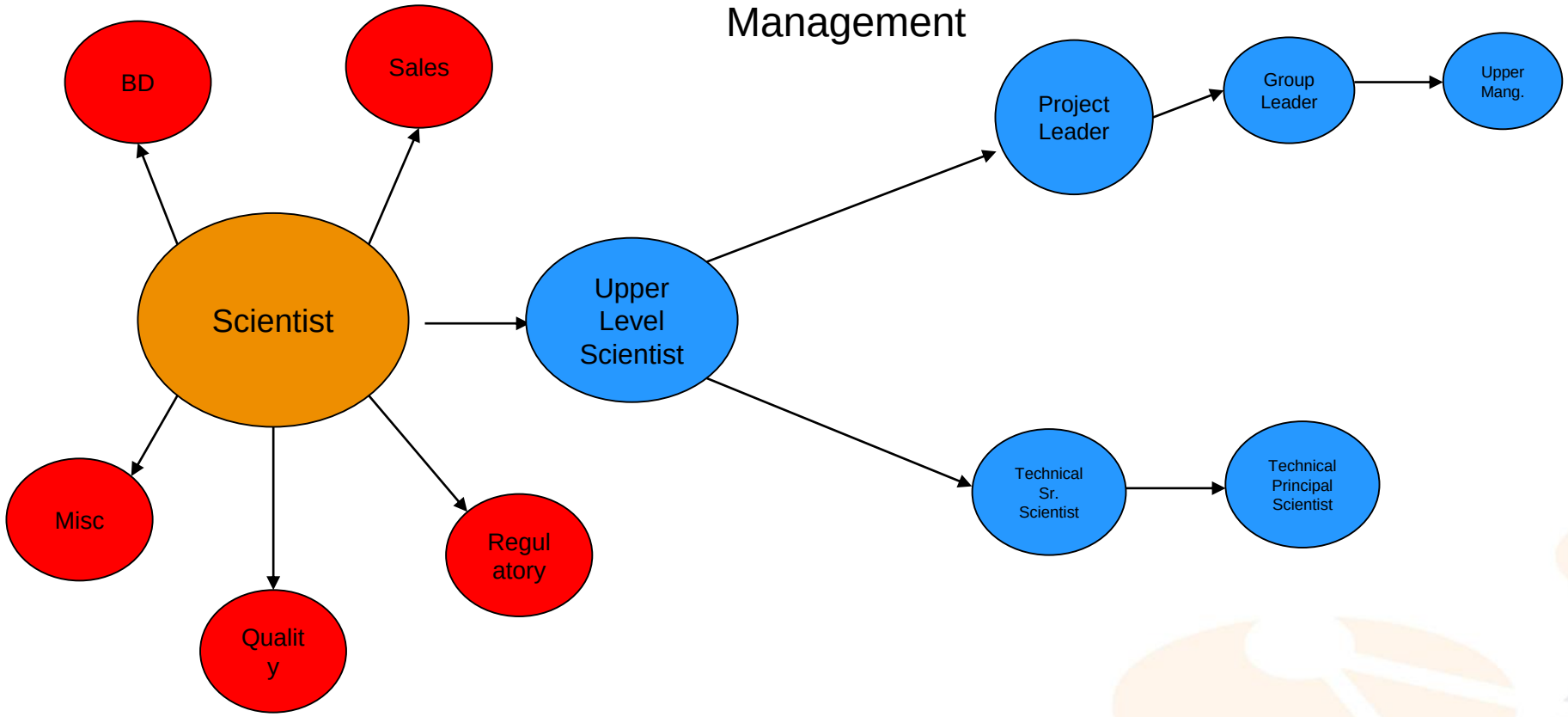
1. Do you need to make your own hours?
2. Are you a micromanager?
3. Do you define success in publications?
4. Do you like to work on a project from start to finish (concept to final product)?
5. Do you like to manage your own time while at work?
6. Do you have to work on new tasks everyday?
7. Do you love to attend conferences?
8. Do you value work life balance?

# Typical Day for a Process Development Scientist

- Analytical
  - Run a Test Method (HPLC, Western, ETC)
  - Attend a Client Meeting
  - Review Data
  - Develop a Method
- Upstream
  - Check on cell culture
  - Review Data
  - Attend Client Meetings
  - Optimize Process Changes
- Downstream
  - Attend a Meeting
  - Lab Tasks
  - Analyze Data
  - Purification Development

Average Time Responsibilities:
50% Lab
20% Data Review
20% Client Meetings
10% Admin

# Career Paths



# Still want to go to industry?

- Helpful tips when looking and applying for jobs:
  1. What is on your resume that will help you land that job?
  2. Reach out to people at company's you are interested in before you want to apply for jobs.
  3. Write a specific cover letter for the job you are applying for an tailor your resume to that job.
  4. Learn about the company and position you will be interviewing for during the phone interview.
  5. During your onsite presentation make sure to “know your audience”

# Example Application

**Profile**

- Highly skilled and versatile analytical chemist.
- 3+ years of biopharmaceutical analytical method development experience.
- 5 years industry experience in a GLP/GMP laboratory environment setting at KBI Biopharma, Eurofins-AvTech, and Pfizer.
- Experienced chemical biologist with 4 years of experience in an academic laboratory at the University of North Carolina at Chapel Hill
- Applies creative interdisciplinary approaches to analytical method development and optimization for biological and chemical entities.
- Seeks and implements initiatives to improve workflow.
- Builds and leads successful teams with more than 2 years of management experience.
- Six Sigma Green Belt Certified.

**Technical Laboratory Skills**

- Analytical chromatography
  HPLC/UPLC (RP, SEC, IEX, Affinity), FPLC, TLC, LCMS (TOF), GC, CE (CGE, cIEF, iCE), SDS-Page,
- Microscopy (fluorescence)
  Widefield, Confocal (scanning and spinning disc)
- Spectroscopy
  UV-Vis, Spectrofluorometry, Plate Reader (absorbance, luminescence, and fluorescence), NIR, Raman Scattering, IR
- Bacterial cell culture
  *E.coli*
- Mammalian cell culture
  HUVEC, MCF-7, HeLa, Jurkat, MEC-10, erythrocytes
- Immune based assays
  Western, Depletion, Immunochemisty (microscopy and flow cytometry), ELISA
- Other analytical techniques
  Karl-Fisher, qPCR, Southern Blot, Northern Blot

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**Position Description**

Job Description:

- Supports upstream cell culture development efforts in the development and manufacturing areas. Conceptualizes, proposes and executes process development studies for client projects, primarily for mammalian cell culture. Includes experimental design, set-up, maintenance and harvest of shake flasks, bench-scale bioreactors and 50 L and 200 L single-use bioreactors (SUBs).
- Technical transfer of upstream cell culture processes to manufacturing based on development studies. May provide technical support for cGMP manufacturing.
- Responsible for producing high quality documentation and client reports suitable for publication and regulatory requirements.
- Works toward developing a broad knowledge of state of the art principles and theory; may provide technical leadership in the group, lead in-house technical development projects and may serve as in-house advisor on key scientific discipline areas.
- May be called upon to be a project team leader of a development program that includes the following duties:
- Direction and administrative duties including the coordination of efforts of team members and across departments; Acting as spokesperson on development programs and interact positively and productively with clients; Advising management on program status.
- Responsible for developing/maintaining a current understanding of cGMP and other regulatory requirements.
- Adheres to all safety requirements and assures that departmental employees comply with required safety procedures.
- Able to react to change productively and handle other essential tasks as assigned.

Job Requirements:

- B.S. degree and 9 years of related experience; M.S. and 7 years of related experience or Ph.D. and 2+ years related experience in a scientific discipline.

Job Description:

- Demonstrated ability to independently troubleshoot technical challenges, and complete projects/assignments within given timelines with limited direct supervision.
- Independently design experiments aimed to develop analytical test method for use in process development support and ultimately cGMP testing.
- Regularly exercises technical discretion in the execution and interpretation of experiments that contribute to project goals.
- Develop and execute experiments in support of process development.
- Understands experiments and conducts troubleshooting analysis.
- Required: Well versed in development of cell based assays and maintaining cell lines.
- Familiar with protein characterization techniques such as: HPLC, Capillary Electrophoresis, SDS-PAGE, Western Blot, UV-Vis.
- Maintains familiarity with current scientific literature.
- Maintains and updates knowledge of instrumentation.
- Notebook upkeep and sound scientific writing and communication skills.
- Assures proper labeling, handling, and storage of all chemicals used in the area; assures proper labeling and disposition of hazardous waste in satellite areas; adheres to all safety requirements and follows safe procedures, and attends all required safety and health training, including handling hazardous waste.
- Able to react to change productively and handle other essential tasks as assigned.

Job Requirements:

- B.S. degree and 7 years of related experience; M.S. and 5 years of related experience or Ph.D. in a scientific discipline.

# Remember…

Some succeed because the are destined too, but most succeed because they are determined to.