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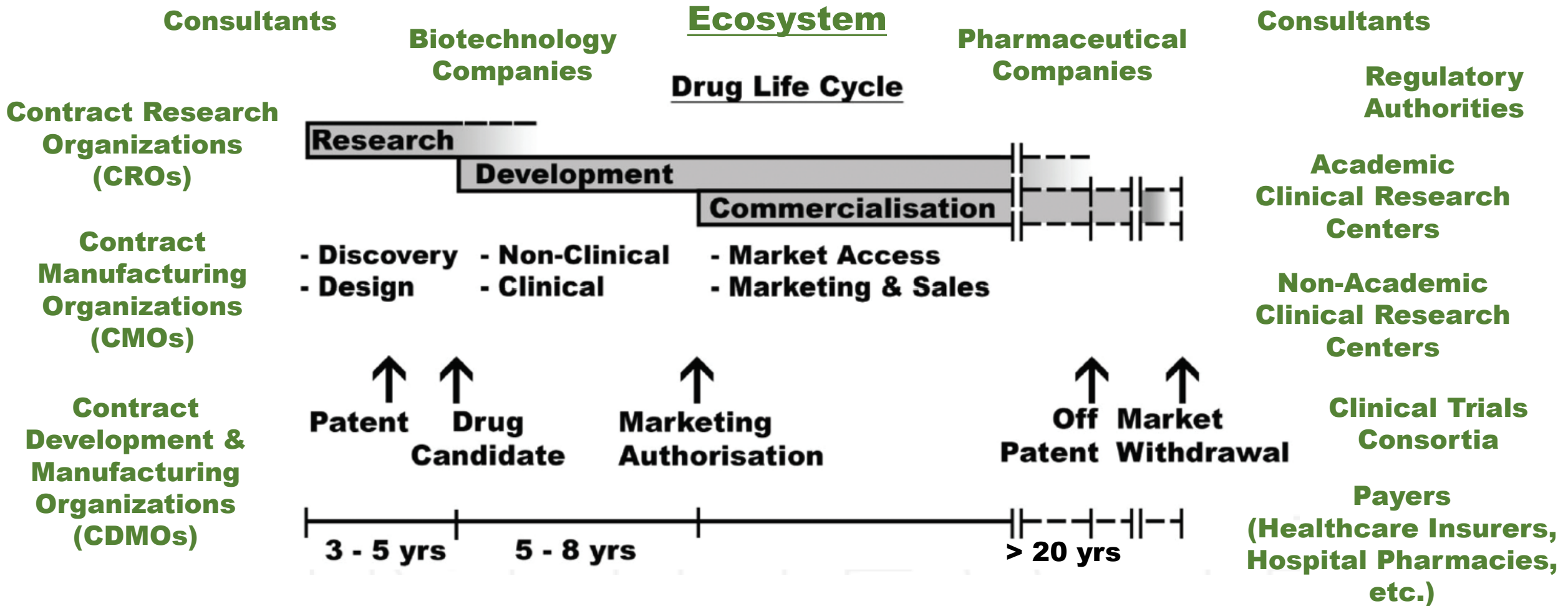
ISP Seminar Series A

Careers Trajectories in the Biotechnology & Pharmaceutical Industry

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What Is the Biotechnology & Pharmaceutical Industry?



Similar life cycles for medical devices (incl. diagnostics), cell therapies, and gene therapies

[Adapted from Thomas et al. \(2016\) Job and Career Opportunities in the Pharmaceutical Sector, In: Special Topics in Drug Discovery, Chen T \(Ed.\), InTech](#)

Areas Covered Today

- Clinical Development
 - Clinical research
 - Clinical operations
 - Medical review & pharmacovigilance
 - Clinical biometry
 - Clinical services
- Commercialization & Medical Affairs
 - Market access
 - Pharmaceutical marketing
 - Pharmaceutical production & distribution
 - Pharmaceutical sales
 - Medical affairs
- Support & Management
 - Regulatory affairs/sciences
 - Quality management
 - Scientific/medical writing
 - Training & development
 - Management

What Is Clinical Development?

- What is it responsible for?
 - Performing all *regulatory studies* of the drug candidate involving *human subjects*
- What does it take?
 - Extensive *collaborations* between *divisions* to generate all clinical data — using good clinical practices (*GCP*) and good manufacturing practices (*GMP*)— required for:
 - Marketing authorization application (*pre-approval phase*)
 - Continued development once the drug is on the market (*post-approval phase*)

What Is Clinical Development?

- Who are involved?
 - Clinical research:
 - Responsible for *content* of *clinical development plan* (CDP; define *strategy*, do *planning*, oversee *methodology*, coordinate *overall management* of clinical *trials*)
 - *Early* Clinical Development (*Phases 0, 1, and 2a*): Clinical pharmacologists, clinical pharmacokineticists, clinicians/clinical scientists (specialists and GPs), ...
 - *Late* Clinical Development (*Phases 2b and 3*): Clinicians/clinical scientists, pharmaceutical physicians, pharmaco-epidemiologists, hospital/clinical pharmacists, ...

What Is Clinical Development?

- Who are involved?
 - Clinical operations:
 - Responsible for *implementation* of *clinical development plan* (local project *management, monitoring* and *administration* of all clinical *trials*)
 - Clinical trial managers, clinical research associates (CRAs or monitors), clinical trial administrators (CTAs)—various backgrounds: biomedical or pharmaceutical scientists, research nurses, physiotherapists, physicians, ...
 - Medical review and pharmacovigilance:
 - Responsible for *critical review* of all *medical data* gathered in clinical *trials*, especially all data on *adverse events* and *adverse reactions*
 - Medical reviewers, pharmacovigilance (PV) experts—various backgrounds: pharmaceutical physicians, hospital/clinical pharmacists, clinical toxicologists, with external help of clinicians and medical specialists for specific problems

What Is Clinical Development?

- Who are involved?
 - Clinical biometry:
 - Responsible for clinical *data management* and *clinical statistics*
 - Clinical trial methodologists, data managers, (big) data scientists/analysts, biostatisticians, computer programmers
 - Clinical services:
 - Responsible for *supplies* and *logistics* of all clinical *study material* (e.g., *supply*, *storage*, and *shipment* of investigational drugs—including placebo and comparators—and central laboratory materials to and from study centers)
 - Pharmaceutical or biomedical scientists/technologists, industrial pharmacists, medicinal chemists, analytical chemists, green chemists, chemical engineers, bioengineers, ...

What Is Clinical Development?

- Who are the employers?
 - Pharmaceuticals and biotechnology companies
 - Contract Development & Manufacturing Organizations (CDMOs)
 - Contract Research Organizations (CROs)
 - Contract Manufacturing Organizations (CMOs)
 - Consultants/consulting companies
 - Regulatory authorities
 - Academic and non-academic clinical research centers
 - Clinical trial consortia (e.g., Alzheimer's Clinical Trial Consortium (ACTC))

What Are Commercialization & Medical Affairs? 9

- What is it responsible for?
 - *Marketing, sales, and proper clinical use/monitoring* of the approved drug
- Who are involved?
 - Market access:
 - Responsible to *negotiate fair drug price* with different *payers* (e.g., national health authorities, healthcare insurers, hospital pharmacies) and *demonstrate added value* to gain acceptable *coverage* or *reimbursement* conditions
 - Financial experts, drug pricing specialists, health technology assessment (HTA) specialists, pharmacoeconomists, core-value dossier writers, pharmaceutical policy experts, marketing specialists, ...

What Are Commercialization & Medical Affairs? 10

- Who are involved?
 - Pharmaceutical marketing:
 - Responsible for *promoting sales* in a *highly regulated environment* (including *market analysis*, *marketing strategy* and *plan*, *marketing channels* and *tools*) over the different phases of the *drug commercial life span* (pre-launch, launch, ascending phase, maturity, and end-stage phase)
 - Product managers (single drug), brand/group product managers (portfolio of drugs in a given therapeutic area)—various backgrounds: marketing specialists, life scientists with MBA

What Are Commercialization & Medical Affairs? 11

- Who are involved?
 - Pharmaceutical production and distribution:
 - Responsible for *manufacturing* of the drug from active pharmaceutical ingredient (*API*) to *end product* according to good manufacturing practices (*GMP*) and its *distribution* to *wholesalers* and to *community* and *hospital pharmacies*
 - Pharmaceutical or biomedical scientists/technologists, industrial pharmacists, medicinal chemists, analytical chemists, green chemists, chemical engineers, bioengineers, mechanical engineers, electrical engineers, supply chain specialists...

What Are Commercialization & Medical Affairs? 12

- Who are involved?
 - Pharmaceutical sales:
 - Responsible for bringing money to *reinvest* in *new drug R&D activities* and provide return on investment (*ROI*) for *shareholders/investors* by *promoting* the approved drug towards *prescribers* (e.g., physicians) or *pharmacists* (for non-prescription (a.k.a. over-the-counter or OTC) drugs)
 - Sales teams of pharmaceutical sales/medical representatives—various backgrounds: bachelors or masters in business or life sciences with strong communications skills and stamina; trained in-house and on the job

What Are Commercialization & Medical Affairs? 13

- Who are involved?
 - Medical affairs (*bridges gap between R&D and Marketing!*):
 - Responsible for:
 - *Scientific* and *medical* aspects of pharmaceutical *marketing*
 - Management of *medical communications* and *publications*, key opinion leaders (*KOLs*), *advisory boards*, and *medical information* (questions/feedback from *health providers* and *patients*)
 - Clinical *drug development* in *post-approval phase* (e.g., investigator-initiated trials (*ITT*))
 - Medical directors, medical advisors, medical science liaison (MSL), medical information manager, pharmacovigilance (PV) experts—background: usually physicians or pharmacists

What Are Commercialization & Medical Affairs? 14

- Who are the employers?
 - Pharmaceuticals and biotechnology companies
 - Consultants/consulting companies
 - Contract Manufacturing Organizations (CMOs)
 - Payers (e.g., national health authorities, healthcare insurers)

What Are Support & Management?

- What is it responsible for?
 - Providing support and management across *all phases* of the *drug life cycle*
- Who are involved?
 - Regulatory affairs/sciences:
 - Responsible for ensuring that:
 - All relevant *legislations, regulations, and guidelines* are followed—at the forefront in *negotiations* with *regulatory agencies* (e.g., asking for scientific advice, discussing issues, arguing about changes)
 - All *regulatory documents* are prepared, assembled, and send to the appropriate health authorities in due time
 - Pharmacists, occasionally other life scientists, often with a post-graduate degree in regulatory sciences or pharmaceutical medicine

What Are Support & Management?

- Who are involved?
 - Quality management:
 - Responsible for ensuring quality assurance (*QA*) of all activities through a set of rules and regulations (good practices or *GxP*), translated into standard operational procedures (*SOPs*)
 - Pharmacists and other life scientists, often with a post-graduate degree in quality management
 - Scientific/medical writing:
 - Responsible for writing *study reports*, *publications*, and *regulatory documents* in accordance with established *rules* and *regulations*
 - Life scientists and translators of varied backgrounds with excellent writing and communication skills

What Are Support & Management?

- Who are involved?
 - Training and development:
 - Responsible for providing *induction training* to newcomers (including company-specific strategic thinking and knowledge transfer) as well as *continuous training* and *development* related to *workplace skills* for all (individuals and teams)
 - Trainers come in all shapes and sizes with excellent communication and teaching skills
 - Management:
 - Responsible for *strategic management* (e.g., innovation, portfolio or risk management, go/no-go decision-making) as well as *operational management* (e.g., project management, clinical, or sales operations)
 - Life scientists to economists and lawyers with different backgrounds and qualifications,, often with an MBA degree

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 - Consultants/consulting companies
 - Payers (e.g., national health authorities, healthcare insurers)
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What Are The Qualifications Needed?

Academic Knowledge Base for Employment		Drug Life Cycle Stage		
Academic Field by Discipline	Academic Degree	Early Clinical Development	Late Clinical Development	Commercialization & Medical Affairs
Medical Sciences	MD, MD/MAS	✓	✓	✓
Medical Sciences	MD/PhD, MD/MAS/PhD	✓✓	✓	✓
Biomedical Sciences	BS, MS, BS/MAS, MS/MAS	✓	✓	✓
Biomedical Sciences	PhD, MAS/PhD	✓	✓	✓
Biology	BS, MS, BS/MAS, MS/MAS	✓	✓	✓
Biology	PhD, MAS/PhD	✓	✓	✓
Biochemistry	BS, MS, BS/MAS, MS/MAS	✓	✓	✓
Biochemistry	PhD, MAS/PhD	✓	✓	✓

[Article: From Medical Practice to Biopharmaceutical Industry Career!](#)

[Adapted from Thomas *et al.* \(2016\) Job and Career Opportunities in the Pharmaceutical Sector, In: Special Topics in Drug Discovery, Chen T \(Ed.\), InTech](#)

What Are The Qualifications Needed?

Academic Knowledge Base for Employment		Drug Life Cycle Stage		
Academic Field by Discipline	Academic Degree	Early Clinical Development	Late Clinical Development	Commercialization & Medical Affairs
Biotechnologies	BS, MS, BS/MAS, MS/MAS	✓	✓	✓
Biotechnologies	PhD, MAS/PhD	✓	✓	✓
Pharmaceutical Sciences	BS, MS, BS/MAS, MS/MAS	✓	✓	✓
Pharmaceutical Sciences	PharmD, MAS/PharmD, PhD, MAS/PhD	✓✓	✓	✓
Pharmacy	BS, MS, BS/MAS, MS/MAS	✓	✓	✓
Pharmacy	PharmD, MAS/PharmD	✓✓	✓	✓

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What Are The Qualifications Needed?

Academic Knowledge Base for Employment		Drug Life Cycle Stage		
Academic Field by Discipline	Academic Degree	Early Clinical Development	Late Clinical Development	Commercialization & Medical Affairs
(Bio)informatics	BS, MS	✓	✓	✓
(Bio)informatics	PhD	✓	✓	✓
Math/Data Analysis	MS, PhD	✓	✓	✓
Chemistry	BS, MS	✓	✓	✓
Chemistry	PhD	✓	✓	✓
Engineering	BEng, BSE, MEng, MSE	✓	✓	✓
Engineering	PhD	✓	✓	✓
Physics	BS, MS	✓	✓	✓
Physics	PhD	✓	✓	✓

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What Are The Qualifications Needed?

Academic Knowledge Base for Employment		Drug Life Cycle Stage		
Academic Field by Discipline	Academic Degree	Early Clinical Development	Late Clinical Development	Commercialization & Medical Affairs
Law	JD	✓	✓	✓✓
Economy/Finance	BA, MA, PhD	✓	✓	✓✓
Business Administration	BA, MBA	✓	✓	✓✓
Communications	BA, MA, PhD	✓	✓	✓✓
Languages/Writing	BA, MA, PhD	✓	✓	✓✓

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Where To Find Job Listings? Websites

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The screenshot shows the Indeed website interface. At the top, there's a navigation bar with links like 'Find Jobs', 'Company Reviews', 'Find Salaries', 'Find Resumes', and 'Employers / Post Job'. The main search area has a 'what' field containing 'Pharmaceutical Industry' and a 'where' field. A blue 'Find Jobs' button is next to the search fields. Below the search bar, there's a tip: 'Tip: Enter your city or zip code in the "where" box to show results in your area.' The left sidebar shows filters for 'Pharmaceutical Industry jobs', 'Sort by: relevance - date', 'Salary Estimate' (ranging from \$45,000 to \$105,000), 'Job Type' (Full-time, Contract, Part-time, Temporary, Commission, Internship), and 'Location' (Cambridge, MA (786)). The main content area displays job listings, including 'Pharmaceutical & Life Sciences, R&D Senior Associate' at PwC, 'Sr. Scientist II Analytical R&D' at Alvogen, and 'Pharmacy Procurement Specialist' at Shopko. A right sidebar offers an email alert subscription for 'Pharmaceutical Industry jobs' with an 'Activate' button.

- Indeed: <https://www.indeed.com/q-Pharmaceutical-Industry-jobs.html>
- Monster: <https://www.monster.com/jobs/search/?q=pharmaceutical-industry>
- LinkedIn: <https://www.linkedin.com/jobs/pharmaceutical-jobs/>
- Pharmiweb.Com: https://www.pharmiweb.jobs/?utm_campaign=2019launch&utm_source=pwp&utm_medium=link&utm_content=pagemoved

Where To Find Salary Ranges?

The screenshot shows the salary.com website. At the top, there's a navigation bar with links for Enterprise, Small Business, and Personal. Below that is a banner for LendingTree with a mortgage rate of 3.04% APR 15 Year Fixed and a loan amount of \$225,000. The main content area is titled "Browse Average Salary Ranges for Pharmaceuticals Jobs" and includes a sub-heading "(Pharmaceuticals Pay Scales)". The text explains that salary ranges vary and provides filters for pay grades: less than \$30K, \$30K-\$50K, \$50K-\$80K, \$80K-\$100K, and more than \$100K. It also offers a search function for all pharmaceutical salaries. Below the text are three dropdown menus for Category (Pharmaceuticals), Industry (ALL), and Income Level (All). On the right side, there's a green sidebar for "Comparison shop for your Home Refinance with LendingTree" with a table of mortgage options.

Term	Rate	APR
30-Year Fixed	3.63%	3.71% APR
15-Year Fixed	2.88%	3.04% APR
5/1 ARM	2.50%	3.70% APR

- salary.com: <https://www1.salary.com/Pharmaceuticals-salaries.html>
- PayScale: <https://www.payscale.com/research/US/Industry=Pharmaceuticals/Salary>
- glassdoor: https://www.glassdoor.com/Salaries/pharmaceutical-salary-SRCH_K00,14.htm

What Is An “Industry-Type” Resume?

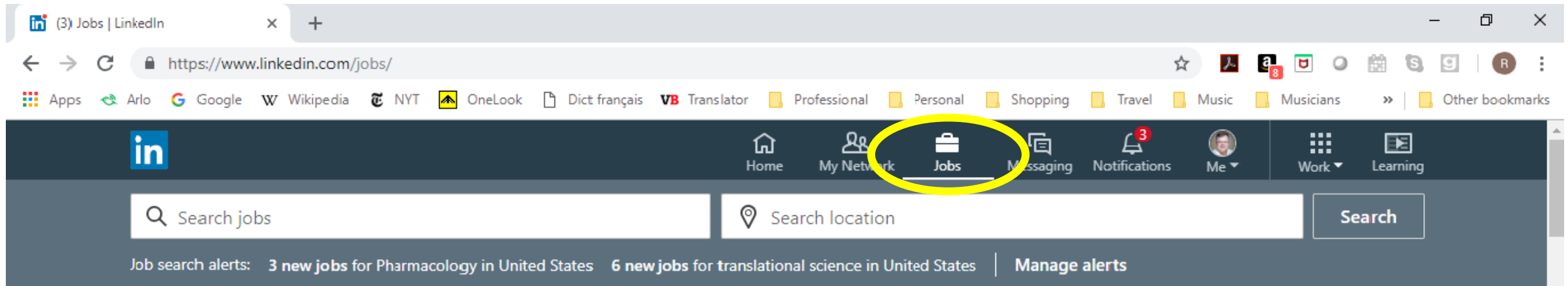
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- Different from “academic-type”
- Events listed starting from most recent
- Typical headers:
 - Summary/Skills: Punchy with keywords!
 - Education
 - Professional Appointments (with responsibilities and “quantitative” accomplishments!)
 - Awards/Research Grants
 - Membership to Professional Societies
 - Publications
- Need to be Applicant Tracking System (ATS) compliant:
 - Example of free-test site: <https://www.zipjob.com/free-review>
- Something to try: Match a job position description to your resume!
 - <https://www.jobscan.co/> (30-day free trial!)

How to Advertise Yourself To Recruiters?

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- If the recruiter or hiring manager phone number is included in the job position ad, call!
- Announce (confidentially) to recruiters on LinkedIn that you are on the market!



You Have Been Selected As Candidate! Now What? 27

- Research the employer ahead of the interviews! Prepare questions about the position, the work environment, and the employer
- Phone interview
- Face-to-face interview (possibly with seminar)
- References (letter of recommendation or short phone interview)
- Always follow up in a thankful manner!