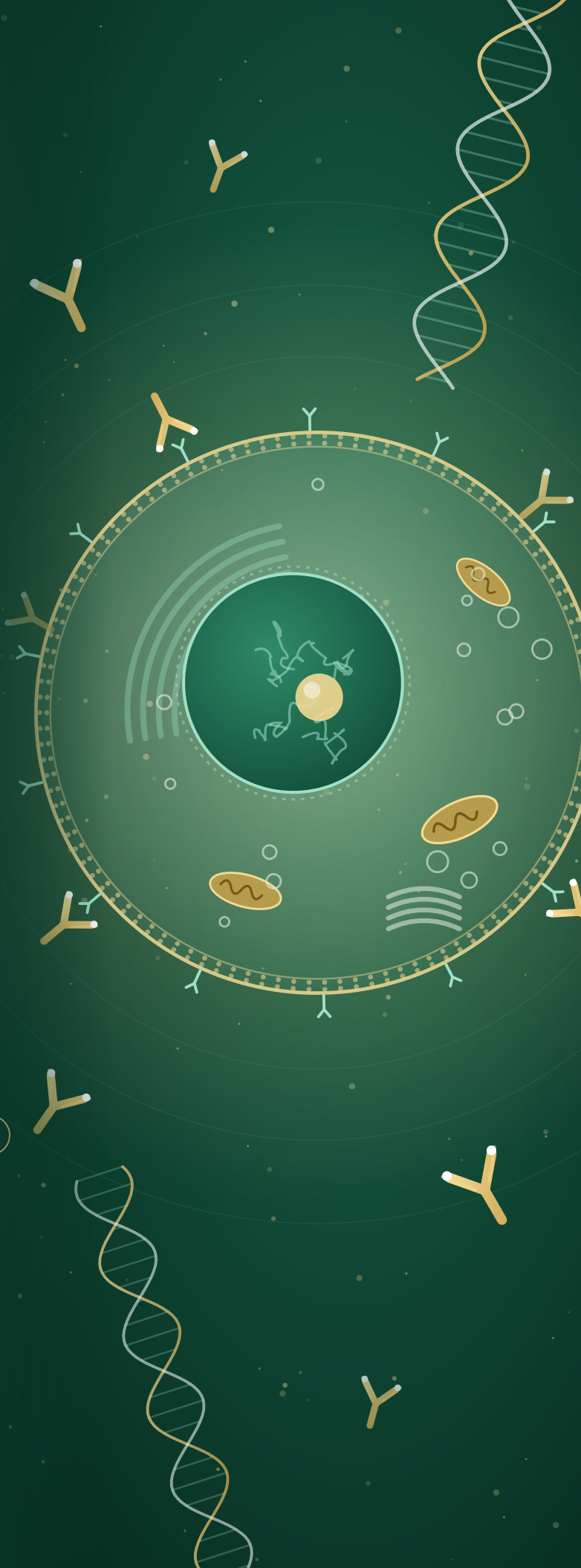
M. Peckable

FREE CAREER RESOURCE · 2026 EDITION

The Biopharma Career *Starter Guide*

How the industry really works, where you fit, and a step-by-step plan to land your first role in the business of making medicine.

- Career Gauge questionnaire
- 9 career paths
- GMP essentials
- Resume translation
- Interview prep
- 90-day plan



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EDUCATION

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Thomas Jefferson University, Jefferson Institute for Bioprocessing · 2021

EXPERIENCE

Myettia is a biopharmaceutical process engineer and scientist whose research and development work spans upstream bioprocessing, viral vector production for advanced therapies, analytical research, and laboratory testing technologies. She has designed and qualified analytical methods, improved laboratory workflows, led scientific investigations, and played a leading role in implementing and qualifying a rapid mycoplasma detection method in a regulated environment.

Beyond the lab, she shares her work through scientific presentations, technical writing, and STEM education, speaking with students and early-career professionals at university programs, industry panels, and networking events.

GOALS

M. Peckable LLC offers career consulting and professional development, including 1:1 career strategy sessions, speaking, and resources like this guide, that help people translate their STEM backgrounds into biopharma careers.

The M. Peckable Collective, a nonprofit organization, is home to the M. Peckable Biopharma Academy, which offers training and mentorship for adult learners. The Collective also works to expand access to STEM education and opportunity, provide education and support for people living with chronic skin diseases such as hidradenitis suppurativa, and host community programs that connect science, patient advocacy, and whole-body stewardship.

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How to use this guide

IF YOU'RE BRAND NEW
Read chapters 1–3 first. They give you the big picture, so job descriptions start to make sense. Then take the Career Gauge.

IF YOU KNOW YOUR TARGET
Jump to your career family in chapter 5, then go straight to the resume, interview, and 90-day plan chapters.

IF YOU'RE CHANGING CAREERS
Start with chapter 7. Your experience counts for more than you think, as long as you translate it.

Myettia's note

I didn't know this industry existed until I already had a bachelor's degree. If you're just now learning that "making medicine" is a career, you are not behind. You're right on time. Most people in this field found it sideways.

TAKE IT ONLINE The Career Gauge is also on the website, with instant results: mpeckablebio.com/#gauge

CHAPTER 01

Biopharma, *explained*

Biopharmaceuticals ("biologics") are medicines made by, or from, living systems: cells, viruses, or biological molecules. They've transformed treatment for cancer, autoimmune disease, rare genetic conditions, and inflammatory diseases like the one I live with.

Traditional "small-molecule" drugs, like aspirin, are built through chemistry. They're small, stable, and can be made the same way every time. Biologics are thousands of times larger and are produced by living cells, which means they're sensitive to everything: temperature, nutrients, timing, contamination. That's exactly why the industry needs so many skilled people: making a biologic consistently and safely at scale takes dozens of specialized roles.

The main types of medicines you'll hear about

TYPE	WHAT IT IS	EXAMPLES & WHAT IT MEANS FOR CAREERS
Small molecules	Chemically synthesized drugs, usually pills.	Most traditional medicines. Careers lean on chemistry, formulation, and analytical testing.
Therapeutic proteins & monoclonal antibodies (mAbs)	Proteins made by engineered cells (often CHO cells) in bioreactors, then purified.	Many cancer and autoimmune treatments. The largest share of biomanufacturing jobs: cell culture, purification, QC, and QA.
Vaccines	Products that train the immune system, including protein, viral, and mRNA-based vaccines.	Large-scale, highly regulated manufacturing with strong demand for aseptic, QC, and microbiology skills.
Cell therapies	Living cells given as medicine, such as CAR-T cells engineered to fight cancer.	Often made for one patient at a time. Hands-on, aseptic work and chain-of-custody tracking.
Gene therapies	Treatments that deliver genetic material, often using viral vectors like AAV or lentivirus.	A fast-growing field. Viral vector production and analytics are specialized, in-demand skills.

Who makes medicine? Types of employers

LARGE BIOPHARMA

Big companies with many products. Structured training, specialized roles, and established systems.

EMERGING BIOTECH

Smaller companies focused on one or a few therapies. More variety, faster change, and broader responsibility.

CDMOS

Contract development and manufacturing organizations make products for other companies. Lots of hiring and fast learning across many projects.

CROS & ACADEMIC MEDICAL CENTERS

Contract research organizations and hospitals run clinical trials on behalf of sponsors.

TOOLS & SUPPLIERS

Companies that make bioreactors, reagents, single-use systems, and instruments. Strong for applications and sales roles.

GOVERNMENT & ACADEMIA

Research institutions, public-health agencies, and university core facilities.

CHAPTER 02

The life of *a medicine*

A new medicine typically takes 10 to 15 years to go from idea to pharmacy, and most candidates never make it. Every stage needs different people. Knowing the stages helps you understand which job posting is which.

Discovery
Find a target and a molecule that affects it.

Preclinical
Test safety and activity in the lab and in animal studies.

Clinical trials
Phases 1–3 test safety and effectiveness in people.

Regulatory review
The FDA or other agencies review all the evidence.

Manufacturing
Make it at commercial scale under GMP.

Post-market
Monitor safety and keep improving the process.

STAGE	WHAT'S HAPPENING	JOBS AT THIS STAGE
Discovery	Scientists study a disease, pick a biological target, and screen or engineer molecules that act on it.	Research Associate, Scientist, Lab Technician, Bioinformatics Analyst
Preclinical	The candidate is tested for activity and safety. In parallel, the team starts developing a manufacturing process and the tests (assays) to measure the product.	Process Development, Analytical Development, Toxicology, Research Associate
Clinical Phase 1	A small group of people, sometimes healthy volunteers, mainly to check safety and dosing.	Clinical Research Coordinator, Clinical Trial Assistant, Clinical Manufacturing
Phase 2	A larger group of patients to see whether it works and find the right dose.	Clinical Operations, Data Management, Process Development (scale-up)
Phase 3	Hundreds to thousands of patients to confirm benefit and monitor side effects.	Clinical Research Associate, Biostatistics, Tech Transfer, Validation
Regulatory review	The company submits a Biologics License Application (BLA) or New Drug Application (NDA). The agency reviews data and inspects manufacturing.	Regulatory Affairs, Quality Assurance, CMC writers
Commercial	Ongoing manufacturing, testing, release, distribution, and safety monitoring (sometimes Phase 4 studies).	Manufacturing, QC, QA, Supply Chain, MSAT, Pharmacovigilance, Medical Affairs

KNOW WHO'S WATCHING

In the U.S., the **FDA** regulates medicines. Within it, **CDER** (Center for Drug Evaluation and Research) oversees most drugs and many therapeutic biologics like monoclonal antibodies, and **CBER** (Center for Biologics Evaluation and Research) oversees vaccines, blood products, and cell and gene therapies. Internationally you'll hear about the **EMA** (Europe) and **ICH**, the group that writes harmonized global guidelines (ICH Q7, Q9, and Q10 come up a lot in quality roles).

Why it matters for you: in every interview, you're being evaluated on whether you'd help the company stay trustworthy to these agencies, and to patients.

CHAPTER 03

How a biologic *is made*

This is my home turf. If you understand this one page, most manufacturing, process development, and QC job descriptions will suddenly make sense.

Cell bank
Frozen vials of carefully characterized cells: the "seed" for every batch.

Upstream
Cells grow in flasks, then bioreactors, and produce the product.

Harvest
Separate the product from cells and debris.

Downstream
Purify, remove viruses and impurities, and concentrate.

Fill-finish
Sterile-filter and fill into vials or syringes.

Upstream: growing the cells

It starts with a vial from the **working cell bank**. Cells (often Chinese Hamster Ovary, or CHO, cells for antibodies; HEK293 cells for many viral vectors) are thawed and expanded in shake flasks, then moved into progressively larger **bioreactors**. These can range from a few liters to thousands of liters, and many modern facilities use **single-use** bioreactor bags instead of stainless steel.

The team controls temperature, pH, dissolved oxygen, and nutrient "feeds" to keep cells healthy and productive. They measure cell density, viability, and **titer** (how much product is being made). For viral vectors, cells are transfected or infected so they produce the vector.

UPSTREAM SKILLS EMPLOYERS LOOK FOR

- Aseptic technique
- Mammalian cell culture
- Cell counting & viability
- Bioreactor operation
- Media preparation
- Metabolite analysis

Downstream: purifying the product

After **harvest** (by centrifugation and/or depth filtration), the product is purified through a series of steps. For antibodies, a typical sequence is **Protein A affinity chromatography** to capture the antibody, a low-pH hold to inactivate viruses, one or two "polishing" chromatography steps (like ion exchange) to remove impurities, **viral filtration**, and **ultrafiltration/diafiltration (UF/DF)** to concentrate the product and swap it into its final buffer.

Each step has to remove specific impurities, such as host-cell proteins, DNA, and aggregates, while keeping as much product as possible. Then the bulk drug substance is sterile-filtered and filled.

DOWNSTREAM SKILLS EMPLOYERS LOOK FOR

- Chromatography (ÄKTA systems)
- Filtration
- Buffer preparation
- UF/DF
- Mass balance & yield

Testing & release: nothing ships until QC and QA say so

At every stage, **Quality Control** tests samples to prove the product is what it claims to be, at the right strength, pure, and safe. Common tests include identity and purity by HPLC or capillary electrophoresis, potency (does it work?) by cell-based assays or ELISA, and safety tests such as **endotoxin**, **bioburden**, **sterility**, and **mycoplasma**. **Quality Assurance** then reviews the full batch record and test results before the batch is released to patients.

Myettia's note

Mycoplasma are tiny bacteria that can contaminate cell cultures without obvious signs. Traditional culture-based testing can take about a month. Part of my work has been helping qualify a rapid mycoplasma detection method in a regulated lab, which means proving with data that a faster method is just as reliable. That's what a lot of this industry is: careful, documented work that gets medicine to patients faster without cutting corners.

TRY THIS Pull up three manufacturing or QC job postings and highlight every word from this page. You'll likely understand far more of them than you did yesterday.

CHAPTER 04

The Career *Gauge*

There's no single "right" job in biopharma, but there are roles that will fit how you think, how you like to work, and what energizes you. Answer each question honestly (pick the one answer that fits best), then tally your points.

FASTER ONLINE Take it at mpeckablebio.com/#gauge for instant results with personalized next steps.

1. You have a free Saturday and a project idea. Which sounds most fun?

- ☐ Testing a hunch with a small experiment, just to see what happens. — RD 2 · PD 1
- ☐ Taking something that already works and making it faster, cheaper, or bigger. — PD 2 · ENG 1 · MFG 1
- ☐ Following a detailed plan precisely and holding a finished product at the end. — MFG 2 · QC 1
- ☐ Getting the paperwork and details perfectly organized so nothing slips through. — QA 2 · REG 1
- ☐ Explaining something complicated to friends until it finally clicks. — BIZ 2 · CLIN 1

2. Where would you like to spend most of your workday?

- ☐ At a lab bench with instruments and samples. — QC 2 · RD 1 · PD 1
- ☐ On my feet in a production suite, hands-on with equipment. — MFG 2 · PD 1
- ☐ At a desk with documents, data, and screens. — REG 2 · QA 1 · ENG 1
- ☐ Out with people: at sites, with customers, patients, or audiences. — CLIN 2 · BIZ 2
- ☐ A mix: moving between the lab, the floor, and my desk. — ENG 1 · PD 1 · QA 1

3. How do you feel about rules and written procedures?

- ☐ I love a clear procedure and doing it right every time. — MFG 2 · QC 2
- ☐ I like knowing the rules best and catching what others miss. — QA 2 · REG 2
- ☐ They're fine, but I want room to try new approaches. — RD 2 · PD 1
- ☐ I'd rather design the system that everyone else follows. — ENG 2 · PD 1 · QA 1

4. Something goes wrong in the middle of a project. You're the one who…

- ☐ Investigates the data and paper trail to find the root cause. — QA 2 · QC 1 · PD 1
- ☐ Rolls up their sleeves and fixes it hands-on. — ENG 2 · MFG 1
- ☐ Designs a new experiment to understand why it happened. — RD 2 · PD 1
- ☐ Calmly keeps everyone affected informed and on track. — CLIN 2 · BIZ 1 · REG 1

5. Which topics pull you in the most?

- ☐ Biology, microbiology, or immunology. — RD 2 · QC 1
- ☐ Chemistry, math, or statistics. — QC 2 · PD 1
- ☐ Engineering, physics, coding, or how machines work. — ENG 2 · PD 1
- ☐ Health, the human body, and patient care. — CLIN 2 · BIZ 1
- ☐ Writing, law, policy, or business. — REG 2 · BIZ 1 · QA 1

6. What's your education so far (completed or in progress)?

- ☐ High school diploma or GED. — MFG 2 · QC 1
- ☐ A certificate or associate degree in science or biotech. — MFG 2 · QC 2
- ☐ A bachelor's degree in science or engineering. — QC 1 · PD 1 · RD 1 · QA 1 · ENG 1
- ☐ A master's degree or PhD in science or engineering. — RD 2 · PD 1 · REG 1
- ☐ A degree outside of science. — BIZ 2 · CLIN 1 · QA 1 · REG 1

7. A role needs full cleanroom gowning (no jewelry or makeup) and may include nights, weekends, or 12-hour shifts. Your honest reaction?

- ☐ Sounds fine, especially if it's my way in. MFG 3
- ☐ Okay now and then, but I'd prefer regular hours. QC 1 · PD 1 · RD 1
- ☐ I'd prefer a desk role with predictable or flexible hours. REG 2 · QA 1 · ENG 1
- ☐ I'd rather have travel and variety. BIZ 2 · CLIN 2

8. Which accomplishment would make you proudest?

- ☐ Data that shows something nobody knew before. RD 3
- ☐ A process that works at 2,000 liters, not just 2. PD 3 · ENG 1
- ☐ A batch I helped make, released on time and on its way to patients. MFG 2 · QC 1 · QA 1
- ☐ An inspection or submission that passed with no findings. QA 2 · REG 2
- ☐ A clinical trial that enrolled the patients it needed. CLIN 3
- ☐ An audience or customer who finally understood, and said yes. BIZ 3

9. What's your favorite way to work with data?

- ☐ Generating it: running the experiments and tests. QC 2 · RD 1 · PD 1
- ☐ Analyzing it: trends, graphs, and patterns. PD 1 · ENG 2 · QA 1
- ☐ Verifying it: checking it's accurate, complete, and compliant. QA 2 · REG 1
- ☐ Honestly, I'd rather work with people than spreadsheets. BIZ 2 · CLIN 1 · MFG 1

10. Which communication style fits you best?

- ☐ Let me focus deeply and let the work speak. RD 1 · QC 1 · ENG 1
- ☐ I write clearly and enjoy getting wording exactly right. REG 2 · QA 1
- ☐ I like coordinating people, timelines, and moving parts. CLIN 2 · PD 1
- ☐ I love presenting, teaching, and persuading. BIZ 3

11. What draws you to biopharma most?

- ☐ Understanding how disease works. RD 2
- ☐ Actually making medicines and getting them to patients. MFG 2 · PD 1 · QC 1
- ☐ Protecting patients by making sure everything is safe and right. QA 2 · REG 1 · QC 1
- ☐ Working directly with patients and clinicians. CLIN 3
- ☐ The technology: automation, equipment, and data. ENG 3
- ☐ The people and business side of science. BIZ 2

12. Which workplace sounds most like you?

- ☐ A large, established company with structured training.
- ☐ A small startup working on one bold new therapy.
- ☐ A fast-paced company making many clients' products.
- ☐ A company making cutting-edge cell or gene therapies.
- ☐ A hospital or research organization running clinical trials.
- ☐ A company that builds the instruments and tools scientists use.
- ☐ A company making medical devices or diagnostic tests.
- ☐ A government, university, or nonprofit lab with a public mission.

Score your *Gauge*

For each answer you checked, add the points shown next to it to the matching boxes below (for example, **RD 2 · PD 1** means 2 points to RD and 1 to PD). Question 12 doesn't score points; it tells you which kind of workplace to explore first.

RD	PD	MFG	QC	QA	REG	CLIN	ENG	BIZ
Research & Development	Process Development	Manufacturing	Quality Control	Quality Assurance	Regulatory Affairs	Clinical Research	Engineering & Data	Science-Facing Business

Reading your results

- **Your top score** is your strongest match. Start your research in that career family (chapter 5).
- **Your second score** is a great "adjacent" option. Many careers move between neighboring families; QC to QA and process development to manufacturing science are both very common moves.
- **A tie** means you have range. Read both profiles and notice which one makes you lean in.
- **Low scores** aren't "can'ts." They're just not your strongest pull right now.

Your Question 12 workplace

IF YOU CHOSE…	EXPLORE
A large, established company with structured training	Large biopharma company
A small startup working on one bold new therapy	Emerging biotech or startup
A fast-paced company making many clients' products	CDMO (contract development & manufacturing)
A company making cutting-edge cell or gene therapies	Cell & gene therapy company
A hospital or research organization running clinical trials	CRO or academic medical center
A company that builds the instruments and tools scientists use	Life-science tools & suppliers
A company making medical devices or diagnostic tests	Medical device or diagnostics company
A government, university, or nonprofit lab with a public mission	Government, academic, or nonprofit research

Myettia's note

Treat your results as a hypothesis, not a verdict. That's how scientists work: form a hypothesis, test it, adjust. Your "experiments" are informational conversations, job descriptions, volunteer roles, and short courses. Chapter 11 shows you how to run them.

CHAPTER 05

Nine career *families*

Job titles vary from company to company, so think in families. Each profile below covers what the work is, who tends to thrive, typical education, titles to search, the skills to build, and where the path can lead.

Discovery Research & Development

RD · You want to be first to know.

Design and run experiments that answer open questions: how a disease works, whether a molecule binds its target, which construct or cell line performs best. You'll plan studies with your team, run assays, analyze data, keep a detailed lab notebook, and present results at lab meetings.

YOU'LL THRIVE IF

You love open-ended problems, you're comfortable with experiments failing (most do), and you can stay patient through long projects.

GROWS INTO

Research Associate II/III → Senior Research Associate → Scientist (a graduate degree often speeds this up) → Principal Scientist or project leadership.

TITLES TO SEARCH

Research Associate I · Research Assistant · Laboratory Technician, R&D · Scientist I

TYPICAL EDUCATION

Bachelor's in biology, biochemistry, chemistry, or related field for associate roles. Master's or PhD for Scientist titles.

SKILLS TO BUILD

Cell culture, molecular biology (PCR, cloning), protein assays (ELISA, western blot), flow cytometry, data analysis (Excel, GraphPad Prism), scientific writing.

Process Development & Tech Transfer

PD · You want it to work at scale, every time.

Turn a process that works in a flask into one that works in a 2,000-liter bioreactor, reliably. Upstream PD teams optimize cell growth and productivity; downstream teams design the purification. You'll run small-scale models, design experiments (DoE), write tech-transfer documents, and support the manufacturing floor when the process moves to the plant. **MSAT** (Manufacturing Science and Technology) teams do similar work for processes already in production.

YOU'LL THRIVE IF

You like optimizing, troubleshooting, and seeing the connection between data and real-world output.

GROWS INTO

PD Associate → Senior Associate → Engineer/Scientist → Process lead, MSAT lead, or tech-transfer manager.

TITLES TO SEARCH

Process Development Associate · Upstream Associate · Downstream Associate · MSAT Associate · Bioprocess Engineer I

TYPICAL EDUCATION

Bachelor's in a life science or chemical, biomedical, or bioprocess engineering. Bioprocess-focused master's programs are a strong accelerator.

SKILLS TO BUILD

Bioreactor operation, chromatography, filtration, design of experiments (DoE), statistics (JMP or Minitab), technical writing.

GMP Manufacturing & Bioprocess Operations

MFG · You want to make the medicine.

Run the equipment that produces medicine for real patients: media and buffer prep, bioreactors, harvest, purification, and fill-finish. Everything happens in a cleanroom and by the procedure, documented in the batch record as you go. In cell therapy, you may process an individual patient's cells. It's hands-on, team-based, and one of the most common ways into the industry, often without a four-year degree.

YOU'LL THRIVE IF

You like hands-on work, take pride in precision, work well on a team, and can handle shifts and gowning.

GROWS INTO

Associate I → II → III → Lead/Supervisor → Manager. Many people also move into QA, MSAT, validation, or training.

TITLES TO SEARCH

- Manufacturing Associate I
- Bioprocess Technician
- Manufacturing Technician
- Production Associate, Cell Therapy

TYPICAL EDUCATION

High school diploma plus a biomanufacturing certificate, an associate degree, or a bachelor's. Requirements vary by company.

SKILLS TO BUILD

Aseptic technique, Good Documentation Practices, cleanroom behavior, following SOPs, basic math for solution prep, teamwork under time pressure.

Quality Control & Analytical Science

QC · You want proof, not assumptions.

Test raw materials, in-process samples, and final product to prove they meet specifications before anything reaches a patient. QC chemistry runs assays like HPLC, capillary electrophoresis, and ELISA. QC microbiology handles endotoxin, bioburden, sterility, mycoplasma, and environmental monitoring of the cleanrooms. Analytical Development designs and validates the methods QC will use.

YOU'LL THRIVE IF

You're meticulous, you enjoy instruments and data, and you understand that "the result is the result," even when it's inconvenient.

GROWS INTO

Analyst I → II → Senior Analyst → QC Supervisor, method validation specialist, or a move into QA or Analytical Development.

TITLES TO SEARCH

- QC Analyst I
- QC Microbiology Technician
- Environmental Monitoring Technician
- Analytical Development Associate
- Sample Management Associate

TYPICAL EDUCATION

Bachelor's in biology, chemistry, microbiology, or related field. Some EM and sample-management roles accept an associate degree.

SKILLS TO BUILD

HPLC, ELISA, qPCR, endotoxin (LAL) testing, aseptic sampling, LIMS, data integrity (ALCOA+), OOS investigations.

Quality Assurance & Validation

QA · You protect patients by protecting the process.

Make sure everything is done right *and* documented right. QA reviews batch records, approves SOPs, oversees deviations and CAPAs, manages change control, and prepares the site for audits and inspections. Validation proves that equipment, processes, cleaning, and computer systems do what they're supposed to do, using protocols like IQ, OQ, and PQ.

YOU'LL THRIVE IF

You notice what others miss, you're comfortable saying "not yet," and you can explain why rules matter without being rigid.

GROWS INTO

QA Associate → Specialist → Senior Specialist → QA Manager, auditor, or Head of Quality.

TITLES TO SEARCH

QA Associate · QA Specialist I · Document Control Specialist · Validation Associate · Compliance Associate

TYPICAL EDUCATION

Bachelor's in science or engineering is common. Document control can be a door-opener for people with strong administrative experience.

SKILLS TO BUILD

Batch record review, deviation and CAPA writing, root cause analysis, risk assessment, technical writing, knowledge of 21 CFR 210/211 and ICH Q9/Q10.

Regulatory Affairs

REG · You translate science into approval.

Be the bridge between the company and health authorities. Regulatory teams plan submission strategy, assemble and publish applications such as INDs and BLAs, answer agency questions, review labeling and promotional materials, and keep the company current as regulations evolve. CMC regulatory specialists focus specifically on manufacturing and quality sections.

YOU'LL THRIVE IF

You love precise writing, organization, deadlines, and understanding the "why" behind the rules.

GROWS INTO

Associate → Specialist → Manager → Director of Regulatory Affairs, or a CMC regulatory specialty.

TITLES TO SEARCH

Regulatory Affairs Associate · Regulatory Coordinator · Regulatory Operations Specialist · Regulatory Publishing Associate

TYPICAL EDUCATION

Bachelor's in a science field. Many regulatory professionals move in from QA, QC, or the lab after a few years. Graduate certificates in regulatory affairs are common.

SKILLS TO BUILD

Scientific and technical writing, document management systems, eCTD structure, familiarity with FDA guidance documents, project management.

Clinical Research & Operations

CLIN · You want to be close to patients.

Help run the clinical trials that test new medicines in people. Coordinators at hospitals schedule visits, consent participants, collect data, and keep regulatory binders current. Sponsor and CRO roles manage sites, track enrollment, and monitor that the protocol and Good Clinical Practice are followed.

YOU'LL THRIVE IF

You're organized and people-centered, you can juggle many details, and you care deeply about participant safety.

GROWS INTO

Coordinator or Trial Assistant → Clinical Research Associate (monitor) → Clinical Trial Manager → Clinical Operations leadership.

TITLES TO SEARCH

- Clinical Research Coordinator
- Clinical Trial Assistant
- Study Start-Up Specialist
- Clinical Data Coordinator

TYPICAL EDUCATION

Bachelor's in health or life sciences is common. Nursing, pharmacy tech, and patient-care backgrounds transfer well.

SKILLS TO BUILD

Good Clinical Practice (GCP), informed consent, EDC systems, HIPAA, scheduling and tracking, clear communication with patients and physicians.

Engineering, Automation & Data

ENG · You want to build the system everyone runs on.

Design, maintain, and improve the equipment, utilities, automation, and data systems behind biomanufacturing. Process and facilities engineers keep equipment and clean utilities (like purified water and clean steam) running. Automation engineers program the control systems. Commissioning and qualification (C&Q) teams prove new equipment is ready. Data teams turn plant and lab data into insight.

YOU'LL THRIVE IF

You like systems thinking, building and fixing things, and solving problems with technology.

GROWS INTO

Engineer I → II → Senior → Lead, project engineering, or digital/automation leadership.

TITLES TO SEARCH

- Process Engineer I
- Automation Engineer
- C&Q Engineer
- Facilities Technician
- Manufacturing Data Analyst

TYPICAL EDUCATION

Engineering degree (chemical, mechanical, electrical, biomedical) for engineer roles. Technician and data roles can accept trade training, associate degrees, or demonstrable skills.

SKILLS TO BUILD

P&IDs, equipment troubleshooting, PLC/DCS basics, data tools (Excel, SQL, Python, Power BI), validation protocols.

Science Communication, Training & Technical Sales

BIZ · You make science make sense.

Use your science with people at the center. Field application scientists help customers get results with a company's instruments. Technical sales and support teams solve customer problems. Training specialists build the programs that onboard new manufacturing staff. Medical and scientific writers create documents, publications, and educational content.

YOU'LL THRIVE IF

You light up when explaining things, you're comfortable presenting, and you like variety and relationships.

GROWS INTO

Specialist → Senior/Lead → Manager of applications, training, or sales; or medical communications leadership.

TITLES TO SEARCH

- Field Application Scientist
- Technical Sales Representative
- Technical Support Specialist
- GMP Training Specialist
- Medical Writer

TYPICAL EDUCATION

Bachelor's in science; hands-on lab experience is a big advantage for application roles. Writing roles often welcome advanced degrees.

SKILLS TO BUILD

Presenting, teaching, writing, CRM tools, deep knowledge of one technology area, and a portfolio of things you've explained.

DON'T OVERLOOK THESE DOORS

Some of the best entry points never show up in a "biotech careers" search: **environmental monitoring technician**, **sample management associate**, **document control specialist**, **warehouse / materials management associate** in a GMP facility, **media and buffer prep technician**, and **glass wash or lab support technician**. They put you inside a regulated facility, teach you GMP, and many companies prefer to promote from within.

Also worth exploring: **supply chain and planning**, **pharmacovigilance** (drug safety), **EHS** (environment, health and safety), and **project management**.

CHAPTER 06

GMP *essentials*

GMP (Good Manufacturing Practice, often written cGMP) is the set of regulations that ensure medicines are consistently made to quality standards. Speaking GMP fluently tells a hiring manager you'll be safe to train.

The core idea

Quality can't be tested into a product at the end. It has to be built in at every step. So GMP asks every company to **say what you do** (written procedures), **do what you say** (follow them exactly), and **prove it** (document it, in real time). In the U.S., the core rules are in **21 CFR Parts 210 and 211**, with additional biologics rules in Parts 600–680 and electronic-records rules in **Part 11**.

"If it isn't documented, it didn't happen."

You'll hear this on day one. Good Documentation Practice (GDP) means recording entries at the time you do the work, in permanent ink, legibly, and signed and dated. Mistakes are corrected with a single line through the error, so the original is still readable, plus your initials, the date, and a reason. Never use white-out, never write over an entry, and never record something before you've actually done it.

ALCOA+ data integrity

LETTER	MEANS
A	Attributable: who did it, and when
L	Legible: readable and permanent
C	Contemporaneous: recorded at the time
O	Original: the first record, or a true copy
A	Accurate: correct and truthful
+	Complete, Consistent, Enduring, Available

CLEANROOMS, GOWNING & TRAINING

Production happens in classified cleanrooms (Grades A–D in EU GMP, or ISO 5–8). Higher grades mean more gowning: coveralls, hood, goggles, sterile gloves, and boots, with no jewelry, makeup, or phones. Expect your first one to three months to be mostly training: reading SOPs, shadowing, and being observed before you work on your own.

The quality system, in plain language

TERM	WHAT IT IS	WHAT IT LOOKS LIKE ON THE JOB
SOP	Standard Operating Procedure: the approved, step-by-step instructions for a task.	You're trained on each SOP before performing it.
Batch record	The step-by-step record of how one batch was made, completed as the work happens.	You execute steps, record values, and sign; critical steps are often second-person verified.
Deviation	Any departure from an approved procedure or expected result.	Report it immediately. Reporting is expected; hiding a deviation is the real problem.
CAPA	Corrective and Preventive Action: fixing the root cause so it doesn't happen again.	You may help investigate, retrain, or revise a procedure.
Change control	The formal process to change anything validated: a procedure, equipment, or material.	Even a "better" way can't be used until it's approved.
OOS	Out of Specification: a test result outside the acceptance limits.	You stop, notify your supervisor, preserve the samples and data, and follow the OOS procedure. You never re-test just to get a passing result.

CHAPTER 07

Translate your *background*

Hiring managers aren't only looking for people who've worked in biopharma. They're looking for evidence that you'll be careful, consistent, coachable, and calm under pressure. That evidence may already be on your resume. You just need to translate it.

IF YOU'RE COMING FROM	YOU ALREADY BRING	STRONG FIRST TARGETS	GAP TO CLOSE
Academic research or a college lab	Techniques, notebooks, troubleshooting, reading literature, presenting data.	Research Associate, Analytical Development, QC Analyst, Process Development	GMP and documentation language; show reproducibility, not just discovery.
Healthcare (CNA, MA, nursing, pharmacy tech)	Patient safety mindset, HIPAA, infection control, charting, procedures. Pharmacy techs may have aseptic (USP <797>) experience.	Clinical Research Coordinator, cell therapy manufacturing, QC microbiology	Learn GCP or GMP vocabulary; frame charting as "documentation."
Food, beverage, or brewing	Sanitation, HACCP, batch production, fermentation, quality checks.	Manufacturing Associate, media/buffer prep, QC technician	Connect HACCP and sanitation logs to GMP and cleaning validation.
Other manufacturing or skilled trades	Equipment operation, lockout/tagout, preventive maintenance, shift work, safety.	Manufacturing Technician, Facilities/Utilities Technician, Calibration	Learn aseptic behavior and documentation expectations.
Military	Discipline, following technical orders exactly, inspections, training others, security clearances.	Manufacturing, Validation, Facilities, QA, Supply Chain	Translate ranks and duties into civilian terms; emphasize documentation and compliance.
Teaching or tutoring	Explaining complex ideas, curriculum design, classroom management, patience.	GMP Training Specialist, Field Applications, Science Communication, Lab roles	Pair teaching with technical exposure (a course, certificate, or lab volunteering).
Retail, hospitality, or customer service	Inventory, cash handling accuracy, opening and closing checklists, staying calm with the public.	Materials Management, Sample Management, Document Control, Technical Support	Quantify accuracy and reliability; add a short GMP or biotech course.
Administrative or office work	Organization, record keeping, scheduling, version control, attention to detail.	Document Control, Regulatory Operations, Clinical Trial Assistant, QA Associate	Learn the document lifecycle (draft, review, approve, effective, retire).
IT, data, or software	Systems thinking, databases, scripting, troubleshooting.	Manufacturing data, LIMS/MES administration, automation, CSV (computer system validation)	Learn 21 CFR Part 11 and data-integrity expectations.

Myettia's note

After my bachelor's, I worked as a substitute teacher. At the time it felt like a detour. Looking back, standing in front of a room every day taught me to explain complex ideas simply, adapt fast, and stay composed, and I still use all of that. Nothing you've done is wasted if you learn how to talk about it.

CHAPTER 08

A resume that *speaks industry*

Most resumes are read in seconds, and often by software first. Yours needs to match the job's language, prove your skills with specifics, and be easy to scan.

The structure that works

1. **Header:** name, city and state, phone, email, LinkedIn URL.
2. **Summary (2–3 lines):** who you are, your target role, and your strongest proof. *"Biology graduate with 18 months of hands-on mammalian cell culture and aseptic technique, seeking a Manufacturing Associate role in cell therapy."*
3. **Technical skills:** techniques, instruments, and software grouped by category. This is where keyword matching happens.
4. **Experience:** reverse chronological, 3–5 bullets each, starting with strong verbs.
5. **Education, training & certifications:** include relevant courses and GMP or GCP training.

KEEP IT CLEAN One page early in your career; two if you have significant experience. Use simple formatting with no tables, text boxes, or graphics, so screening software can read it.

The bullet formula

> *Action verb + what you did + how (tools, methods, standards) + result or scale.*

STRONG VERBS FOR THIS INDUSTRY

Executed · Documented · Performed · Maintained · Verified · Troubleshot · Optimized · Qualified · Investigated · Trained · Reconciled · Analyzed

MAKE IT MEASURABLE

Numbers make bullets believable: how many samples, cell lines, batches, people trained, percent improvement, error rate, or time saved. Estimate honestly if you don't have exact figures.

Before & after (illustrations only; always use your own true numbers)

BACKGROUND	BEFORE	AFTER
College lab	Did cell culture for a research project.	Maintained 4 mammalian cell lines using aseptic technique in a BSL-2 lab; recorded passages and observations in a bound notebook with no contamination events over 9 months.
College lab	Ran ELISAs.	Performed 30+ sandwich ELISAs following a written protocol; generated standard curves and analyzed results in GraphPad Prism for weekly lab meetings.
Pharmacy tech	Filled prescriptions and compounded medications.	Prepared sterile compounded preparations in an ISO 5 hood following USP <797> and pharmacy SOPs; double-verified calculations and labels with zero dispensing errors in 2 years.
Retail	Managed inventory.	Reconciled inventory for 1,200+ items weekly, investigating discrepancies and documenting corrective actions; reduced count variances by 30%.
Food service	Kept the kitchen clean.	Executed daily sanitation and temperature logs per HACCP food-safety plan; passed 3 health inspections with no critical findings.
Teaching	Taught science classes.	Delivered standards-aligned lessons to classes of 25–30 students, adapting instruction in real time; designed hands-on demonstrations to explain complex concepts.

Keywords by career family

Mirror the exact phrases a job posting uses, but only for skills you genuinely have or have studied. These are the words that often appear in postings for each family.

FAMILY	KEYWORDS TO LOOK FOR (AND USE HONESTLY)
Research & Development	cell culture, aseptic technique, molecular cloning, PCR/qPCR, ELISA, western blot, flow cytometry, assay development, data analysis, lab notebook, literature review
Process Development	upstream, downstream, bioreactor, chromatography, filtration, UF/DF, scale-up, scale-down model, DoE, tech transfer, process characterization, single-use
Manufacturing	cGMP, batch record, SOP, aseptic processing, cleanroom, gowning, media/buffer preparation, equipment cleaning, documentation, shift work
Quality Control	HPLC, ELISA, qPCR, endotoxin/LAL, bioburden, sterility, mycoplasma, environmental monitoring, LIMS, OOS, method transfer, data integrity
Quality Assurance	batch record review, deviations, CAPA, change control, root cause analysis, audits, 21 CFR 210/211, document control, validation, IQ/OQ/PQ, risk assessment
Regulatory Affairs	IND, BLA, NDA, eCTD, CMC, submissions, FDA guidance, labeling, regulatory intelligence, publishing, health authority correspondence
Clinical Research	GCP, ICH E6, informed consent, IRB, protocol, EDC, source documents, adverse events, site management, enrollment
Engineering & Data	P&ID, commissioning, qualification, utilities, PLC/DCS, automation, preventive maintenance, MES, Python, SQL, data visualization, CSV
Science-facing business	customer training, technical support, product demonstrations, presentations, CRM, scientific writing, applications support

LinkedIn in 30 minutes

- **Headline formula:** *Target role | strongest skill area | what you care about*. For example: "Aspiring QC Analyst | Microbiology & Aseptic Technique | Passionate about patient safety."
- **About:** 3 short paragraphs: your story, your skills, what you're looking for.
- **Skills section:** add the keywords from your target family above.
- **Open to Work:** list specific titles and locations; recruiters filter by them.
- **Featured:** pin a project, poster, presentation, or certificate.

Tailor in 15 minutes per job

1. Paste the posting into a document and highlight required skills in one color, preferred in another.
2. Make sure your summary names the role.
3. Reorder your skills so the posting's top requirements appear first.
4. Adjust 2–3 bullets to echo the posting's language, truthfully.
5. Save as *FirstName-LastName-Role-Company.pdf*.

CHAPTER 09

Networking *without the awkward*

Networking isn't asking strangers for jobs. It's collecting information from people who already do the work, so you can make better decisions and so they remember you when an opening appears. Many roles are filled through referrals.

Who to contact

- Alumni from your school working in biotech (use LinkedIn's alumni search).
- People 2–5 years into the role you want. They remember being new.
- Speakers and attendees at local life-science events, career fairs, and professional chapter meetings.
- Instructors and staff at training programs and community colleges.

Connection request (under 300 characters)

Hi [Name], I'm a [your background] exploring careers in [QC / manufacturing / etc.] and saw your work at [Company]. I'd love to connect and learn from your path. Thank you!

Asking for a 15–20 minute conversation

Thank you for connecting, [Name]. I'm working toward my first role in [field], and your move from [their background] into [their role] really stood out to me. Would you be open to a 15-minute call in the next few weeks? I'd love to hear what your team does day to day and what skills you think matter most for someone starting out. I'm happy to work around your schedule.

12 great questions to ask

1. What does a typical week look like for you?
2. How did you get your first role in the industry?
3. What do new people on your team usually struggle with?
4. Which skills matter most that aren't obvious from job postings?
5. What does your team look for when hiring entry-level people?
6. Which titles should I search for that I might be missing?
7. How do people usually move up or across from your role?
8. What training or certifications actually made a difference for you?
9. What do you enjoy most, and what's hardest?
10. What's the culture like in a GMP environment at your company?
11. Is there anything on my resume you'd change for this kind of role?
12. Is there anyone else you'd recommend I talk to?

The follow-up (send within 24 hours)

Thank you again for your time today, [Name]. Your advice about [specific thing] was so helpful, and I've already [action you took]. I'll keep you posted on my progress. If I can ever be helpful to you, please let me know.

Myettia's note

Before I met my first research mentor, Dr. Zhang, I spent weeks filling a notebook with questions and notes. I was nervous, but that preparation is what impressed him, and it turned a summer program into years of mentorship. You can't control who says yes, but you can always control how prepared you are when they do.

CHAPTER 10

Interview *like an insider*

Biopharma interviews test three things: can you do the work (or learn it), will you follow the system, and will you tell the truth when something goes wrong. That third one matters more than most candidates realize.

Use the STAR method for every story

Situation
Set the scene in one or two sentences.

Task
What were you responsible for?

Action
What did *you* do? (The longest part.)

Result
What happened, and what did you learn?

Behavioral questions and what they're really asking

QUESTION	WHAT THEY'RE LISTENING FOR
Tell me about a time you made a mistake.	Honesty, ownership, and how fast you reported it. Never say you don't make mistakes.
Describe a time you followed a detailed procedure.	Precision, patience, and respect for written instructions.
Tell me about a time you disagreed with a coworker.	Professionalism, and escalating through proper channels.
How do you handle repetitive work, or learning something new fast?	Focus, consistency, and coachability. Much of GMP work is repetition done perfectly.
Describe working under time pressure.	Staying accurate when rushed: "I don't skip steps."

GMP scenario questions

SCENARIO	A STRONG ANSWER INCLUDES
You notice a coworker signed for a step they didn't perform.	You don't ignore it or fix it yourself. You raise it with your supervisor or QA according to site procedure. Patient safety and data integrity come first; it's not about blame.
You made an error on a batch record.	Correct it per Good Documentation Practice: a single line through, initial, date, and reason. Never obliterate. If it affects the product, report a deviation.
Your test result is out of specification.	Stop, don't re-test on your own, preserve the sample and data, notify your supervisor, and follow the OOS procedure.
An experienced operator says, "We always do it this way," but it differs from the SOP.	Follow the approved SOP. Raise the discrepancy. If there's a better way, it gets changed through change control.
You're unsure about a step during production.	Pause and ask before proceeding. Guessing is never acceptable.

Technical topics to review

- **Lab roles:** aseptic technique, pipetting and dilution math, standard curves, controls, contamination prevention.
- **Manufacturing & PD:** the upstream/downstream flow in chapter 3, what a bioreactor controls, why we filter.

Smart questions to ask them

- What does training look like for someone new in this role?
- What would success look like in my first 90 days?
- What's the shift schedule, and how do people rotate?
- What do people who thrive on this team have in common?

- **QC:** specifications, system suitability, positive and negative controls, OOS handling.
- **QA:** deviation vs. CAPA vs. change control, ALCOA+.
- **Clinical:** informed consent, adverse event reporting, ICH GCP principles.

- How have people grown from this role?

ALWAYS Send a short thank-you email within 24 hours that mentions one specific thing you discussed.

THE RECRUITER PHONE SCREEN

- Have a 60-second "tell me about yourself" ready: background, skills, why this role.
- Know your availability for shifts and your earliest start date.
- Research typical pay for the role and location beforehand, so you can answer salary questions with a range.

THE NIGHT BEFORE

- Reread the job posting and your tailored resume.
- Pick your 5 best STAR stories and say them out loud.
- Look up what the company makes and where it is in development.
- Prepare 3 questions to ask.

PANEL & SITE INTERVIEWS

- Expect to meet several people: a manager, peers, and sometimes QA.
- A site tour is part of the interview. Be curious and respectful of gowning and safety rules.
- Thank each interviewer by name.

AFTER EVERY INTERVIEW Write down the questions that stumped you and how you'd answer them now. Over time, that list becomes your best study guide, and a "no" becomes practice for the next "yes."

CHAPTER 11

Your 90-day *launch plan*

Three to five focused hours a week is enough to make real progress. Adjust the pace to your life. Consistency beats intensity.

DAYS 1–30 · EXPLORE

Weeks 1–2

- [ ] Take the Career Gauge and write down your top two families.
- [ ] Read your families' profiles in chapter 5.
- [ ] Save 10 real job postings in those families.
- [ ] Highlight the skills that repeat across postings.

Weeks 3–4

- [ ] List 15 employers within commuting distance (or remote).
- [ ] Complete one free GMP or GCP introductory course.
- [ ] Rewrite your resume with the bullet formula.
- [ ] Update your LinkedIn headline and About section.

DAYS 31–60 · CONNECT & BUILD

Weeks 5–6

- [ ] Send 10 connection requests to people in your target roles.
- [ ] Request 3 informational conversations.
- [ ] Write 5 STAR stories (use the worksheet).
- [ ] Pick one skill gap and start closing it.

Weeks 7–8

- [ ] Hold at least 2 informational conversations; send thank-yous.
- [ ] Attend one career fair, webinar, or local industry event.
- [ ] Create a tailored resume for each of your two families.
- [ ] Ask someone in the industry to review your resume.

DAYS 61–90 · APPLY & REFINE

Weeks 9–10

- [ ] Apply to 3–5 well-matched roles per week.
- [ ] Log every application in your tracker.
- [ ] Message a contact at each company you apply to, if you have one.
- [ ] Practice GMP scenario answers out loud.

Weeks 11–12

- [ ] Follow up on applications after 7–10 business days.
- [ ] Do a mock interview with a friend or mentor.
- [ ] Review: which applications got responses, and why?
- [ ] Set your goals for the next 30 days.

Myettia's note

When I was in college, I let an entire summer slip by without investing in myself, and I promised myself the next one would be different. That promise led me to my first research program, and everything after. Ninety days from now will arrive either way. Let it arrive with you further along.

CHAPTER 12

Training, credentials *& resources*

You don't need every certificate. You need the right next step for your target role. Start free, then invest when you know your direction. Always check providers' websites for current costs, formats, and eligibility.

OPTION	WHAT IT IS	BEST FOR
Community college biomanufacturing & biotech programs	Short certificates and associate degrees with hands-on lab training, often designed for career changers. Examples include North Carolina's BioWork program and similar programs in many states.	Manufacturing, QC technician, and lab support roles
Biotility BACE credential	The Biotechnician Assistant Credentialing Exam from the University of Florida's Biotility program, used by many high school and college biotech programs.	Students and entry-level lab candidates
Jefferson Institute for Bioprocessing (Philadelphia)	Graduate programs and hands-on bioprocessing training courses on industry-scale equipment.	Process development, manufacturing, and anyone wanting real bioprocess experience
NIIMBL	The National Institute for Innovation in Manufacturing Biopharmaceuticals supports workforce programs, including the NIIMBL eXperience, which introduces students to biopharmaceutical manufacturing careers.	Undergraduates and early-career learners
Good Clinical Practice (GCP) training	Free and low-cost GCP courses are widely available online, including through NIH-supported programs. Many research sites also require CITI training.	Clinical research roles
ASQ certifications	The American Society for Quality offers credentials such as Certified Pharmaceutical GMP Professional (CPGP) and Certified Quality Auditor (CQA). Most require work experience.	QA, a mid-career goal
RAPS Regulatory Affairs Certification (RAC)	The leading regulatory affairs credential, from the Regulatory Affairs Professionals Society.	Regulatory affairs, after some experience
ACRP and SOCRA certifications	Clinical research professional certifications (such as CCRC and CCRP), typically requiring documented experience.	Clinical research, a 1–2 year goal
Professional societies	ISPE (pharmaceutical engineering), PDA (Parenteral Drug Association), and local chapters host events, training, and student memberships.	Networking and continuing education in every family

Free resources worth your time

- **FDA.gov:** guidance documents, warning letters (real examples of what goes wrong), and drug approval news.
- **ICH.org:** the Q-series quality guidelines.
- **ClinicalTrials.gov:** see which companies are running trials, and where.
- **BioSpace, LinkedIn Jobs, Indeed, and BioPharmGuy:** job searches and company directories.

Philadelphia-area starting points

Greater Philadelphia is nicknamed "Cellicon Valley" for its many cell and gene therapy companies. Start with:

- Life Sciences Pennsylvania (the statewide industry association)
- The Keystone LifeSci ecosystem map of regional organizations
- University City Science Center programs and events
- The Pennsylvania Biotechnology Center in Bucks County

CHAPTER 13

The *glossary*

Sixty terms you'll hear in your first month. Learn the bold word, and you'll be able to follow almost any team meeting.

AAV (adeno-associated virus): a viral vector commonly used to deliver gene therapies.

ALCOA+: data integrity principles (see chapter 6).

Aseptic processing: handling sterile materials without introducing contamination.

Assay: a test that measures something about a sample.

Batch record (BR / eBR): the step-by-step record of how a batch was made; "e" means electronic.

Bioburden: the number of microorganisms present on or in a material.

Biologic: a medicine made from or by living systems.

BLA: Biologics License Application, submitted to the FDA to market a biologic.

Bioreactor: a controlled vessel where cells grow and make product.

Biosafety cabinet (BSC): a ventilated enclosure for working safely and aseptically with cells.

CAPA: Corrective and Preventive Action.

CAR-T: a cell therapy in which a patient's T cells are engineered to attack cancer.

CDMO: Contract Development and Manufacturing Organization.

Cell bank (MCB / WCB): master and working banks of frozen, characterized cells.

cGMP: current Good Manufacturing Practice.

Change control: the formal process for approving changes.

CHO cells: Chinese Hamster Ovary cells, the workhorse for making antibodies.

Chromatography: separating molecules by passing them through a column of resin.

Cleanroom: a controlled environment with limits on airborne particles and microbes.

CMC: Chemistry, Manufacturing, and Controls, the manufacturing section of a regulatory submission.

CPP: Critical Process Parameter, a setting that affects product quality.

CQA: Critical Quality Attribute, a product property that must stay within limits.

CRO: Contract Research Organization.

Deviation: a departure from an approved procedure or expected result.

DoE: Design of Experiments, a statistical approach to testing many variables efficiently.

Downstream: the purification part of the process.

Drug substance / drug product: the purified active ingredient / the final formulated, filled medicine.

EDC: Electronic Data Capture, used to collect clinical trial data.

Endotoxin: fever-causing molecules from bacteria, tested by LAL or recombinant methods.

Environmental monitoring (EM): testing air and surfaces in cleanrooms.

Fill-finish: filling product into vials or syringes and sealing them.

GCP: Good Clinical Practice, the standards for running clinical trials.

GDP: Good Documentation Practice.

Gowning: putting on cleanroom garments in a qualified sequence.

HPLC: High-Performance Liquid Chromatography, an analytical separation technique.

IND: Investigational New Drug application, needed before human trials in the U.S.

IQ / OQ / PQ: Installation, Operational, and Performance Qualification.

IRB: Institutional Review Board, which protects research participants.

Lentivirus: a viral vector often used to engineer cells, such as CAR-T.

LIMS: Laboratory Information Management System.

mAb: monoclonal antibody.

MES: Manufacturing Execution System, often used for electronic batch records.

MSAT: Manufacturing Science and Technology.

Mycoplasma: tiny bacteria that can contaminate cell cultures; a required safety test.

OOS / OOT: Out of Specification / Out of Trend.

Potency: a measure of a product's biological activity.

Protein A: a chromatography resin that captures antibodies.

QA / QC: Quality Assurance (systems and oversight) / Quality Control (testing).

Root cause analysis: finding the underlying reason a problem happened.

Scale-up: moving a process to larger volumes.

Single-use: disposable bioreactor bags, tubing, and filters that replace stainless steel.

SOP: Standard Operating Procedure.

Specification: the approved acceptance criteria for a test.

Sterile filtration: filtering through a 0.2-micron filter to remove bacteria.

Tech transfer: moving a process from one team or site to another.

Titer: the concentration of product, or of virus, in a sample.

UF/DF: ultrafiltration/diafiltration, used to concentrate and buffer-exchange product.

Upstream: the cell-growth part of the process.

Validation: documented evidence that something consistently works as intended.

Viral vector: a modified virus used to deliver genetic material.

CHAPTER 14 · WORKSHEET

My Gauge *& skills plan*

MY TOP CAREER FAMILIES

WHY THESE FIT ME (IN MY OWN WORDS)

THE WORKPLACE I'LL EXPLORE FIRST

THREE TITLES I'LL SEARCH EVERY WEEK

Skills gap map

SKILL THE POSTINGS ASK FOR	I HAVE IT	PARTLY	NOT YET	HOW I'LL BUILD IT

STAR story bank

THEME	SITUATION & TASK	ACTION	RESULT
Followed a procedure precisely			
Made a mistake and owned it			
Solved a problem			
Learned something fast			
Worked on a team under pressure			

Application *& networking tracker*

COMPANY	ROLE OR CONTACT	DATE	STATUS	NEXT STEP & DATE

Monthly reflection

WHAT'S WORKING?

WHAT WILL I CHANGE NEXT MONTH?

WHAT'S NEXT

You don't have to *do this alone.*

If this guide helped you find your direction, I'd love to help you take the next step. M. Peckable exists to open the doors that were hard for me to find: through mentorship, education, and a community of people who believe your background is an asset, not an obstacle.

Free consultation

A 30-minute conversation to talk through your goals and where to start.

1:1 Career Strategy Session

A focused session on your resume, target roles, and a personalized plan.

The Academy

Join the waitlist for cohort-based training and mentorship as programs open.

Book and learn more at mpeckablebio.com · mpeckablebio@gmail.com
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