GetReskilled

CPD certificate

in eBioPharma Validation (DT 698) (for Vets)

Part Time | Online

Contents

Make a Career Change into the Pharmaceutical Manufacturing Industry in the Shortest Time Possible with this Online Program

Why Switch to Pharma?

The pharmaceutical manufacturing industry provides a unique opportunity for veterans or military personnel looking to choose a civilian career.

- Provide for your family with a well-paid, stable and secure job.
- The average US salary in pharmaceutical and medical device manufacturing is $99,555.
- This sector has consistently shown growth, even during times of national financial difficulty.
- The pharmaceutical industry has a range of opportunities that suit many military backgrounds.
- This is an industry that will recognise and value your military experience - your skills are needed here.

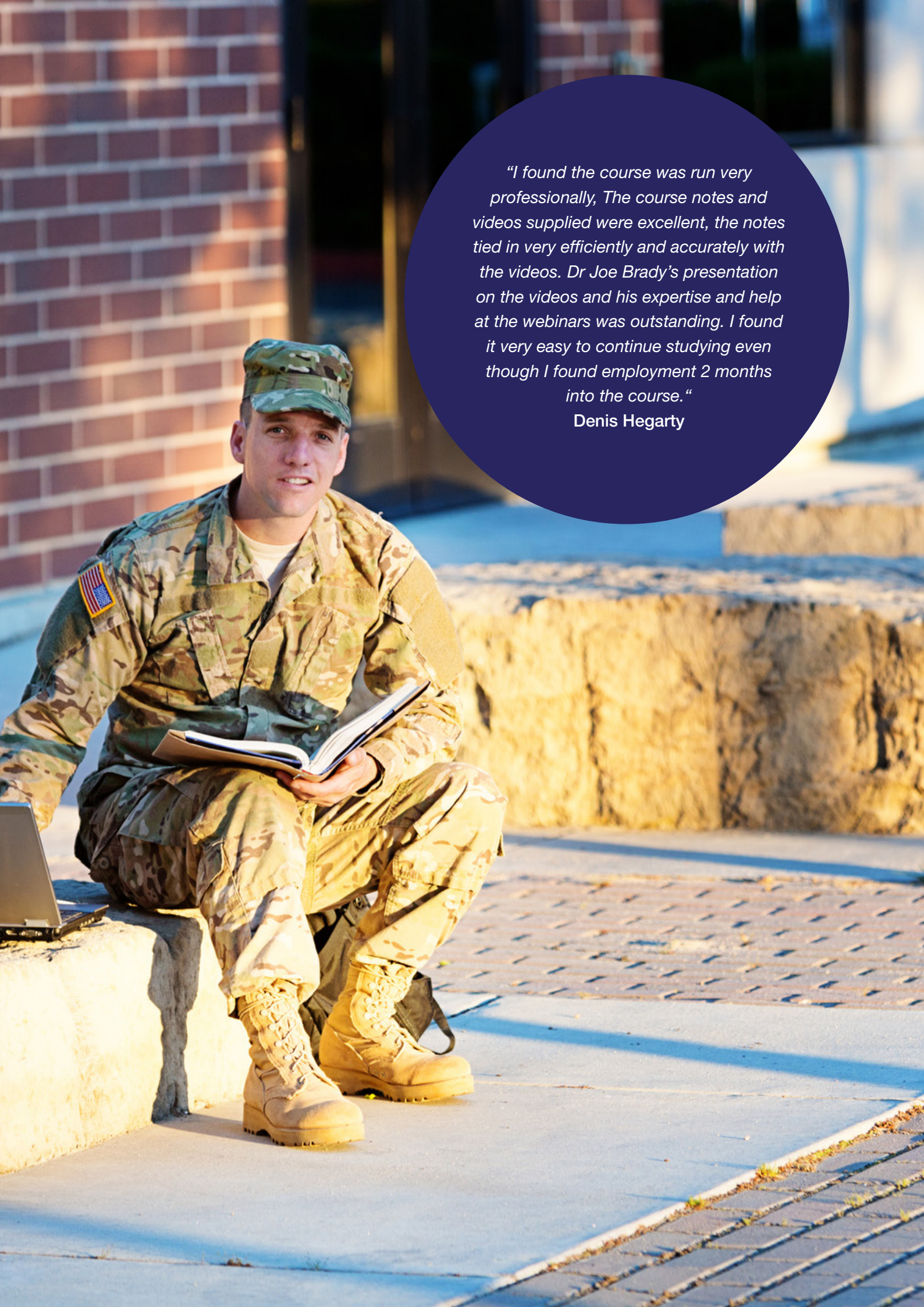
And you don’t need a degree or science background to get started. With this program, you could be job-ready in just 4 months.

Programme Overview

The **Certificate in e-BioPharma** Validation is a 12-month, part-time, online programme. You will develop the skills and knowledge necessary to take up a job similar to your current role but within the Pharmaceutical / MedTech manufacturing industry.

This course covers the modern BioPharmaceutical science and engineering concepts along with the equipment, processes, facilities and systems which you need. You will learn the processes used to manufacture these products in line with the various worldwide regulations and current Good Manufacturing Practices (cGMP) guidelines.

- **Retrain for a New Career** - 80% of our trainees secure new employment within 6 months - 40% actually secure employment before they even graduate.
- **Academically Accredited by the Dublin Institute of Technology, Ireland** - This certification along with the portfolio building assignments that you'll complete during the programme will confirm your capabilities for the manufacture safe medicines, to potential employers.
- **Delivered Online** - This course is delivered online so you can complete it from the comfort of your own home, at your own pace, and get the qualification you need to get a start a new career in this sector.
- **Build a Portfolio** - The program is designed so that end of module assignments can be compiled into a portfolio for students to take to job interviews and demonstrate their knowledge.
- **Gain Transferable Skills** - In addition to the technical materials covered, you'll also gain transferable skills including working on your own initiative, report writing, communication and IT skills.
- **Study all the way to a Degree** - The Certificate in e-BioPharma Validation qualification accounts for the first 50% of a BSc degree in the Manufacture of Medicinal Products (DT-291). Once you've completed this programme, you might choose to apply to study our eManufacturing modules, which make up the final 50%.



"I found the course was run very professionally, The course notes and videos supplied were excellent, the notes tied in very efficiently and accurately with the videos. Dr Joe Brady's presentation on the videos and his expertise and help at the webinars was outstanding. I found it very easy to continue studying even though I found employment 2 months into the course."

Denis Hegarty

Career Coaching Included

The programme includes a concurrent 25-week Advanced Job Hunting Skills course. Our HR specialists will guide you along the complex path of getting a job in this hi-tech, highly regulated manufacturing sector. Over the 25 weeks, you will complete a minimum of 100 job applications.

Who is this course for?

This will depend on background and rank grade. Veterans with the following backgrounds

- Engineering, Science & Technical
- Healthcare/Medical
- Electronic/Electrical Technician
- Transportation & Material Handling
- Combat Specialty (Artillery)

And the following Rank Grades

- E3 - E7

If your rank grade is E8 or higher you may and you have a relevant background, you may already be able to get you foot in the door but you would probably require more training for specialist roles.

"I can Study Around Work and Family Commitments"

"I decided to take the course with GetReskilled as I wanted to return to work and gain experience. I also like the fact that the Certificate is part of a Degree programme.The online experience is working well for me as I study around work and family commitments.

I would also recommend this course for anyone that wants to make the transition into the Pharmaceutical and Medical Device Manufacturing industry and is interested in building a successful career in this area.

The companies I applied for were impressed. I am currently working in Boston Scientific manufacturing Balloon Catheters that are used in Gallstone patients."

Regina McNamara - Boston Scientific

What jobs can I get? Will the salary allow me to comfortably take care of my family?

Yes, according to the Bureau of Labor Statistics, these industries pay between 20% to 30% more than average mean salary. Your exact salary will depend of course on your specific role, your level of experience and your location.

The following salary numbers taken from the United States Bureau of Labor Statistics (BLS) will give you a rough idea of what to expect.

Please note that these are **average median wages** for these roles within the pharma and med devices sectors so do expect some variation **both up and down**.

If you have an Engineering or Technical background...

...check out these **Manufacturing roles**

Many veterans have a good understanding of the link between leadership and production, quality, safety, maintenance, and procedural compliance. They are able to communicate and build teams from the individual to the plant level.

- **Process Technician** (average salary $46,850)
  This is a typical entry-level role.
- **Packaging Operator** (average salary $30,910)
  This is a typical entry-level role.
- **Production Supervisor** (average salary $55,800)

...and check out these **Engineering / Maintenance Roles**

Many veterans and military personnel are highly skilled in using technology as they troubleshoot and repair electronic, electrical, and mechanical systems in the toughest of environments. Those with automation and maintenance experience are perfectly suited to roles which involve the installation, calibration, and servicing of capital equipment.

- **Maintenance Technician** (average salary $62,950)
  This is a typical entry-level role.
- **Calibration Technician** (average salary $45,420)
  This is a typical entry-level role.
- **Facilities Engineer** (average salary $73,300)
- **Process Engineer** (average salary $88,530)

- **Project Engineer** (average salary $99,250)
- **Manufacturing Engineer** (average salary $88.530)

If you have a Science/Lab, Healthcare or Medical Background...

...Check out these **Science Roles**

- **Laboratory Technician** (average salary $49,770)
  With relevant experience, this can be an entry level role.
- **Microbiologist** (average salary $76,850)

...and check out these **Quality Roles**

Many Veterans make good candidates for compliance and quality related positions. Safety compliance and procedural compliance are taught and reinforced in the military and these skills readily translate into the highly regulated manufacturing environment of pharmaceutical or medical device manufacturing. Veterans with this skill set can easily understand the cGMP (current good manufacturing practices) and SOPs (standard operating procedures) that are essential here.

- **Quality Assurance Associate** (average salary $48,550)
  With some quality experience, this can be an entry-level role.
- **Quality Control Associate** (average salary $48,550)
  With some quality experience, this can be an entry-level role.
- **Documentation Specialist** (average salary $47,500)
  With some relevant experience, this can be an entry-level role.
- **Quality Engineer** (average salary $99,250)

If you have an Information Technology/Automation Background...

...check out these **Specialised Roles**

With advanced specialist training, many veterans and military personnel would make ideal candidates for the following specialist and highly paid roles.

- **Automation Engineer** (average salary $96,350)
- **Validation Technician** (average salary $71,000)
- **Validation Engineer** (average salary $90,010)

Skills

For each of these roles, while a degree can be useful, it is certainly not always necessary to work in the industry. The key skills need to work in the industry are:

- **Attention to detail** – you must follow SOP's (Standard Operating Procedures) closely and must observe all features of the clean room environment thoroughly.
- **Alert** – you must be able to quickly identify when the process is deviating from the norm.
- **Calm under pressure** – you must be able to confidently address problems if they arise, take appropriate action and involve others when needed.
- **Numerical skills** – there can be formulas to follow and numerical factors to consider when following protocols and procedures.
- **Good communication skills** – good writing skills are important to ensure clear documentation. Good verbal and listening skills are important to ensure efficient transfer of information between staff members (keeping in mind that these might be high pressure situations when troubleshooting problems).
- **Good computer skills** – much of the documentation of processes is done via computer systems.

What is an example of a company I could work for?

Our previous graduates have gone on to work for companies including **Pfizer, Johnson & Johnson, Novartis, Roche, GSK, Teva, Sanofi, Amgen, Abbott, Abbvie, Boston Scientific, Stryker, Mylan, Bristol-Myers Squibb (BMS), MSD, Merck Group, Gilead Sciences, Regeneron, Medtronic, GE Healthcare, Lilly, West Pharma, Jazz Pharmaceuticals, Zimmer Biomet, Becton, Dickinson & Co** and many more.

Where are the jobs located?

Companies in these industries also tend to be found in clusters. This is when many companies grow within a small geographic location. Examples of cluster locations for these industries include:

- Pennsylvania
- New Jersey
- Raleigh-Durham, North Carolina
- Maryland/DC Metro
- San Diego
- Massachusetts
- Seattle, Washington
- Chicago
- Los Angeles
- San Francisco, Bay Area
- Long Island
- Denver Colorado
- Minneapolis/St Paul

"You can study in your own time & at home (so you don't have travel & child minding costs"

""It has been a great course to re-familiarise myself with the area after such a long time away. I is also brilliant that you can study in your own time & at home (so you don't have travel & child minding costs). I found the pace of the course good and really enjoyed it."

Trish Kineen - Johnson&Johnson

“This course is excellent. It is very well delivered through weekly lectures and webinar tutorials which entail self-assessments at the end of each week and gave me invaluable experience required to advance in this new sector.”

Louise Dineen

Program Content

Code	Title
VOMP3001	Fundamentals of Pharmaceutical Manufacturing Technologies
VOMP3002	Commissioning & Qualification of Equipment Systems
VOMP 3018* VOMP3019*	Practical BioPharmaceutical Processing / Aspects of Regulatory Science in Pharmaceutical Manufacturing
VOMP3006	Pharmaceutical Facility Design
VOMP3008	Planning a Validation Strategy
VOMP3011	From URS to PQ – A Practical Validation Strategy

VOMP 3001 Fundamentals of Pharmaceutical Manufacturing Technologies:

This module will give you a broad understanding of pharmaceutical manufacturing technologies, the rules that govern manufacturing and the guidelines on how these rules are applied along with the risk management tools to be used when making decisions that could impact the safety of the medicines being manufactured.

- Manufacturing Safe Medicines
- GMP's and Quality Management Systems
- Good Automated Manufacturing Practices (GAMP)
- API Manufacturing Technologies
- Biopharmaceutical Manufacturing Technologies
- Cleaning Validation
- Medical Devices and Sterile Manufacturing
- PQ OQ IQ

Towards the end of the module you will be given a graded assignment to complete at home and submit for grading.

VOMP 3002 Commissioning & Qualification of Equipment Systems:

This module explains the engineering documentation used to specify and design equipment or systems in a manufacturing facility – and how to develop the test protocols (IQ, OQ) to ensure that it operates as intended and meets the regulatory requirements.

- Interpreting P&ID's
- System Impact Assessment & Traceability Matrix
- Installation Tests & Equipment Verification
- Piping Isometrics & Checksheets
- Instrument Loops & Checksheets
- URS & Functional Testing
- Assembling the Validation Protocol
- Validation Protocol Final Review

Towards the end of the module you will be given a graded assignment to complete at home and submit for grading.

VOMP 3019 Aspects of Regulatory Science in Pharmaceutical Manufacturing*

This module will explore the emerging regulations and guidelines for manufacturing in an FDA regulated environment through the lens of newly emerging tools to manage product risk, so as to develop an understanding of the role played by OPEX and how leading Quality Metrics can be used in a predictive and proactive manner to enhance the quality and performance of the product over the manufacturing phase of the lifecycle.

- Emerging Regulations in Regulatory Science
- The Product Life Cycle
- Quality Risk Management Tools
- Risk Communication / Mitigation / Management
- Heuristics
- OPEX Tools and Implementation
- Lagging Quality Metrics
- Leading Quality Metrics

Towards the end of the module you will be given a graded assignment to complete at home and submit for grading.

VOMP 3006 Pharmaceutical Facility Design

In this module you will receive a strong grounding in the modern pharmaceutical science and engineering concepts of the environmental controls (air) and clean utility systems design that underpin an aseptic manufacturing facility and the quality systems used in this highly regulated environment to ensure the manufacture of safe and effective medicines for the public.

- Controlling Air Quality and Clean Utilities Manufacturing Logistics Calculations
- Purified Water Generation and Distribution
- Clean Steam and Sterilization
- Controlling Material and Personnel flows
- Aseptic Processing and Vial Filling
- Controlling Cleanrooms and Automation
- Quality Systems for Cleanrooms
- Construction Lifecycle for New and Modified Facilities

Towards the end of the module you will be given a graded assignment to complete at home and submit for grading.

VOMP 3008 Planning a Validation Strategy

This module will give you a broad understanding of how to develop a Validation Master Plan (VMP) for a typical product lifecycle and to prepare the Process Validation Protocol for presentation during a regulatory audit.

- What's new in Validation and in Quality
- ISPE Guidance Documents and ASTM E2500
- Preparing for Process Validation
- The Quality Plan, Change Control and the Validation Master Plan (VMP)
- Process Validation
- The Process Validation Report
- Cleaning Validation
- Health & Safety at the Operator/Product Interface

Towards the end of the module you will be given a graded assignment to complete at home and submit for grading.

VOMP 3011 From URS to PQ – a Validation Project

This is a workshop-driven module where you will develop a P&ID and then back-engineer it into a URS (User Requirement Specification) which will be used to identify the key process measurements that will form the basis of the Performance Qualification (PQ) test script.

Supplementary Content: Generation of Piping and Instrumentation Diagrams, URS for Hot Detergent and Hot PUW Generation and Distribution Skid System, Equipment List, Instrument List (Incl. both an Attachment and Video Link), Inline Components List (Incl. both an Attachment and Video Link), Piping Line List (Incl. both an Attachment and Video Link), P&ID Instrument Identification (Incl. Video Link Only)

- P&IDs
- URS Matrix
- Workshop
- Workshop
- Workshop
- Workshop
- PQ Template
- PQ Template

Towards the end of the module you will be given a graded assignment to complete at home and submit for grading.

Admission Criteria

This is a technical training programme for people coming from a manufacturing, science, engineering, quality or logistical background looking to work in production, engineering and quality roles within the pharmaceutical, biopharmaceutical or medical device manufacturing sector.

Recognised prior learning (RPL) will be taken into account in assessing applicants for this programme.

"I found this course very beneficial and I am delighted that, even at early stages in the course, it has already provided me with the opportunity to secure a position within the pharmaceutical industry."

David O'Shea

Format and Delivery

- Each week, you'll complete a series of videos, quizzes, interactive activities and projects through our online platform, available to access 24/7.
- Online courses can start off great, but staying motivated can be a challenge. So, you'll get regular feedback reports (and emails or phone calls if you fall behind!) to keep you on track.
- Because it's online, there are no long commutes, traffic jams or crowded trains to deal with on the way to class. Study at home after the kids have gone to bed.
- Your working schedules are unpredictable so we offer flexible delivery. Slow down, speed up or pause the delivery of the course.

Duration

The programme will take approximately 12 months, dependent on class schedule.

Acreditation

The completion of all six modules will lead to an academically accredited CPD certificate in eBioPharma Validation (DT7202) awarded by the Dublin Institute of Technology. This forms 50% of a Baccalaureate Degree (DT291) in the Manufacture of Medicinal Products.

Why GetReskilled?

We have retrained over 3,350 experienced workers in the last 10 years into new jobs and careers. These people have come from engineering, science, maintenance, quality and manufacturing backgrounds in other industries and sectors. In addition:

1. 81% of our 2016 graduates found a new job in 6 months, with over 40% of them securing a new position even before they completed our programme.
2. Our graduates have gone on to work for the world's leading blue chip pharmaceutical and medical device manufacturing companies such as **Pfizer, Johnson & Johnson, Novartis, Roche, GSK, Teva, Sanofi, Amgen, Abbott, Abbvie, Boston Scientific, Stryker, Mylan, Bristol-Myers Squibb (BMS), MSD, Merck Group, Gilead Sciences, Regeneron, Medtronic, GE Healthcare, Lilly, West Pharma, Jazz Pharmaceuticals, Zimmer Biomet, Becton Dickinson** and many more.

3. We're serious about helping you find a job. As well as your pharma course, you'll have access to our career coaching program where we'll teach you how to find a job in this sector. And we produce a huge amount of resources to help you with your job hunt.
4. Our programs are supported by Governments in both Ireland (through the Springboard+ Program) and in Singapore (via the WDA) – two of the world's major pharmaceutical manufacturing hubs.
5. Most importantly, our courses are **academically accredited by the Dublin Institute of Technology** which is backed and funded by the Irish Government and is:
    - Largest University in Ireland
    - A World Top 2% Times Higher Education (THE) ranked University
    - 20,000 registered students and over 2,000 members of staff
    - Member of the European University Association.

"I landed my Dream Role as a Project Engineer"

*"I took GetReskilled's 8 month eBioPharmaChem Course and started in an entry level role at **Pfizer**. I kept studying and I eventually leveraged my experience and academic qualifications and landed my dream job as a Project Engineer with the engineering consultants, **Project Management**"*

Declan O'Shea - PM Group

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