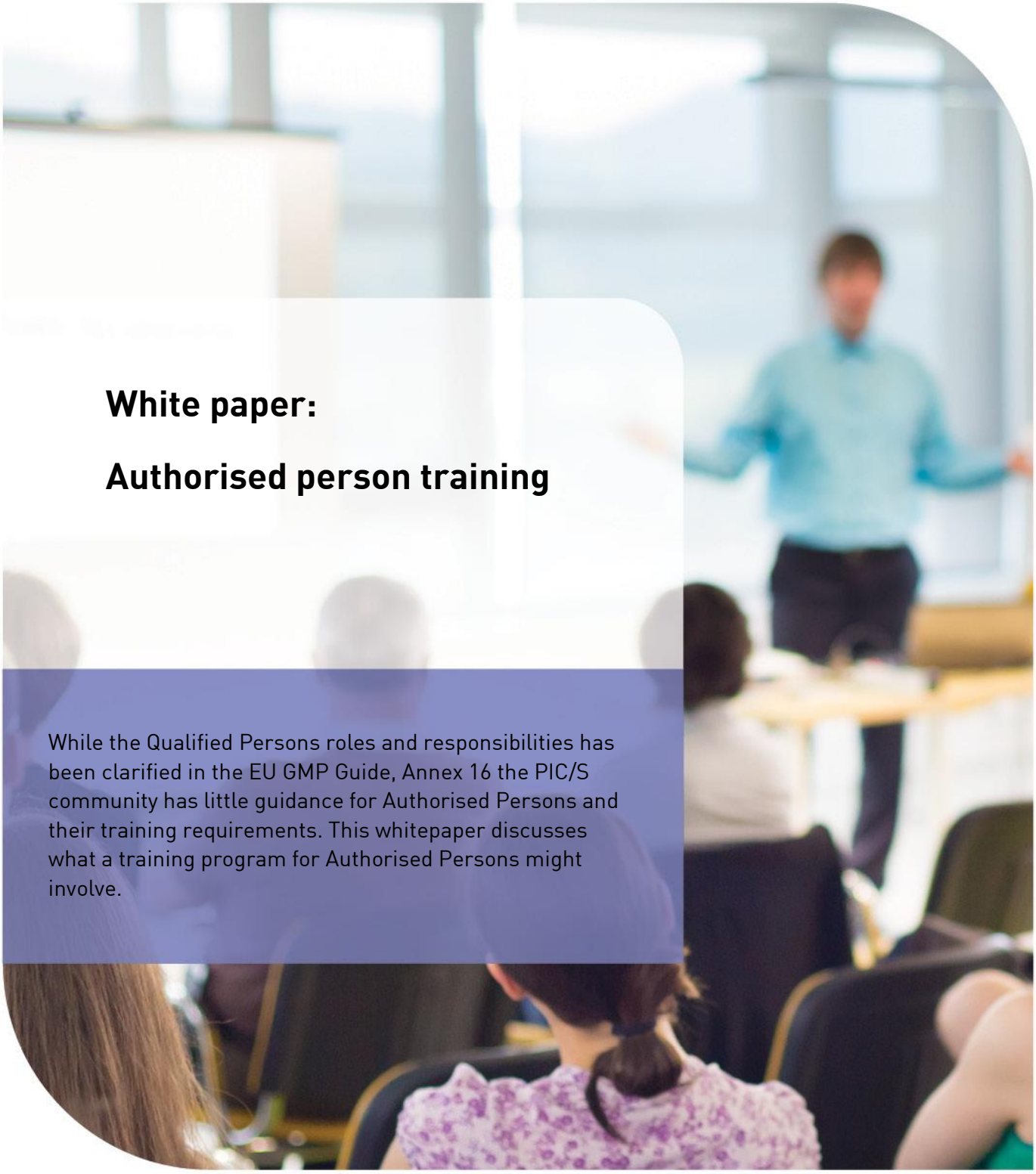

White paper:

Authorised person training

While the Qualified Persons roles and responsibilities has been clarified in the EU GMP Guide, Annex 16 the PIC/S community has little guidance for Authorised Persons and their training requirements. This whitepaper discusses what a training program for Authorised Persons might involve.

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Introduction

The TGA recently released Guidance on Release for Supply for Medicinal Manufacturers, June 2013 (draft guidance document). This draft guidance document recognises the Australian system of release for supply by an Authorised Person (AP) is different from the European system of batch release by a Qualified Person (QP).

The TGA guidance is required because Annex 16 of the EU GMP Guide has not been adopted by PIC/S, leaving industry with an information gap.

The TGA draft guidance document states:

> *1.4 The AP is authorised by the manufacturer through a statement in the manufacturer's quality management system. The manufacturer takes responsibility to ensure the AP's level of education and expertise using the training arrangements in the manufacturer's quality management system. This is verified by the TGA during inspections.*

The TGA draft guidance document addresses the responsibilities of the manufacturer and AP but does not lay out the expectations for the 'training arrangements' for the role. This has resulted in many questions from industry as to what constitutes sufficient AP training.

Background

In order to effectively take responsibility for release for supply of a finished product batch, an AP should have full access and detailed knowledge and understanding to confirm:

- The batch has been produced and controlled in accordance with the requirements of the Marketing Authorisation.
- The batch has been produced and controlled in accordance with the PIC/S Guide to Good Manufacturing Practice for Medicinal Products (PIC/S Guide to GMP) as defined in the Manufacturing Principles (for domestic sites) or, in the case of a batch manufactured in an overseas country, in accordance with good manufacturing practice standards at least equivalent to that PIC/S Guide to GMP.
- Engagement in Product Quality Reviews.
- Overview of the on-going stability program.

General training requirements

Training is a PIC/S Guide to GMP requirement. Chapter 2: Personnel, states:

> *(2.1) personnel must have necessary qualifications and practical experience to carry out their responsibilites.*
>
> *(2.8) manufacturers are responsible for providing training for all personnel whose activities could affect the quality of the product.*

There are no specific guidelines regarding the content or quantity of continuous professional development required by PIC/S for the Authorised Person.

Based on the AP role requirements and the PIC/S Guide to GMP general training expectations, the AP knowledge areas and an education plan can be developed. Accredited training programs can then be aligned to the knowledge areas and education plan.

How is the EU managing QP training?

If you wanted to become a QP in the EU, there is a range of information, including the EU GMP Guide, Annex 16: Qualified Person and Batch Release, to guide individuals and GMP manufacturers through the role and responsibilities.

As an example, in the UK there are three professional bodies, also known as the Joint Professional Bodies, who administer the Qualified Persons scheme - the Royal Pharmaceutical Society, the Royal Society of Chemistry and the Society of Biology.

These three professional bodies require an applicant for certification as a QP to:

- demonstrate a thorough understanding of the foundation knowledge elements,
- be able to apply his or her knowledge of QMS principles, and
- demonstrate understanding of additional knowledge requirements. These additional knowledge requirements are defined in guidance notes for applicants, study guides and codes of conduct.

The applicant is required to demonstrate their knowledge by referencing products and processes for which they are claiming their qualifying experience, which will apply wholly or in part, to the Manufacturer's Authorisation(s) detailed on their application. This assessment process is aimed at determining applicants' suitability for being named on a company Manufacturer's Authorisation.

In addition to entry level QP training, recurring training is supported by universities and approved private providers.

What might an AP training program contain?

Knowledge areas

Taking into consideration the responsibilities of the AP role, it is possible to establish common foundation knowledge areas and align requirements for:

- pre-requisite education
- experience
- on-the-job
- continuous professional development.

If you were responsible for batch release wouldn't you want to know quality systems were in control, including training, change control, CAPA, deviations and customer complaint management? Period Quality Reviews are a key tool for the Authorised Person to know quality systems are being managed.

The following is an example of core knowledge areas for an AP.

Areas	Content
Foundation knowledge areas	▪ Role and professional duties of an Authorised Person ▪ Quality Management Systems ▪ PIC/S GMP Guide and Annexes
Additional knowledge areas	▪ Pharmaceutical manufacturing ▪ Pharmaceutical packaging ▪ Warehousing ▪ Pharmaceutical microbiology ▪ Sampling, analysis and testing of pharmaceuticals ▪ Active pharmaceutical ingredients ▪ Mathematics and statistics related to pharmaceuticals ▪ Registration of pharmaceutical products

Example education plan

Using the common knowledge areas as a guide the following provides an example of the minimum education requirements for an AP.

Knowledge/Education	Example
Pre-requisite education	Bachelor of Science with major or post graduate studies in GMP or pharmaceuticals
Additional experience	At least 3 years of relevant work experience in GMP pharmaceutical manufacturing or quality control
On-the-job	Internal training based on a documented job role, tracked through Quality Systems. Key areas should include (but not limited to): ▪ Change control ▪ Period Quality Review ▪ Training ▪ CAPA ▪ Deviation management ▪ Customer complaint management ▪ Batch Release ▪ Stability program management
Continual Professional Development	Evidence that their knowledge and experience is up-to-date through continuing professional development as demonstrated by record of successful completion of certified and accredited education courses. Suggested minimum: 30-40 hrs per year of external continuing professional development based on the GMP Knowledge areas in this paper.

Examples of accredited education providers

The following list is an example of accredited education providers whose courses may meet the requirements described in GMP Knowledge Areas in this paper. Other relevant accredited providers exist, these are a sample only to provide insight into course content.

Please note that some courses have been designed for EU Qualified Person qualification however the courses support the knowledge requirements for an AP.

Refer to the Appendix in this document for course overviews.

Note: PharmOut does not endorse or specifically recommend any training course. The following list provides an overview of available course content only.

Region	Course	Appendix
Australia	Swinburne Graduate Certificate of Science (GMP)	A
UK	Manchester University Pharmaceutical Industry Advanced Training (PIAT) (UK) ▪ MSc ▪ PG Dip ▪ PG Cert	B
	NSF-DBA Ongoing and graduate certification in GMP	C
Ireland	University College Cork MSc (Pharmaceutical Technology and Quality systems)	D
	Sligo Institute of Technology MSc in Industrial Pharmaceutical Science	E
	Sligo Institute of Technology BSc (Hons) in Pharmaceutical Science with Drug Development	F

Certified courses

Certified training providers may include:

Professional body	Link
ICH	http://www.ich.org/trainings/ich-trainings.html
ISPE	http://www.ispe.org/cs/education_and_training_section/training http://www.ispe.org/certified-pharmaceutical-industry-professional (Discontinued)
PDA	http://www.pda.org/default.aspx
WHO	http://apps.who.int/prequal/trainingresources/pq_pres/gmptraining/GMPBasicTrai ning.htm
CfPA	http://www.cfpa.com/pharmaceutical-training/

Association membership

Active membership in relevant pharmaceutical associations/professional bodies may supplement training by professional bodies.

Relevant pharmaceutical associations/professional bodies may include (but are not limited to:

- ISPE
- PDA

Definitions

Term	Definition
Accredited course	Includes Universities and Institutes of Technology. Accredited providers have been able to attest to the competency of their course/services and these course/services have met established national and international standards.
Certified training	ISPE, PDA, ISO, DIA are examples of not for profit organisations that may provide certified courses.

References

EU GMP Guide, Annex 16: Qualified Person and Batch Release

Guidance on Release for Supply for Medicinal Manufacturers,' June 2013 (draft guidance document)

PIC/S Guide to Good Manufacturing Practice for Medicinal Products

Sources

Links used within this document are prone to change. Please refer to the appropriate source for the most recent information. We endeavour to keep an up-to-date record of information at www.pharmout.net

Appendix A Graduate Certificate of Science (Good Manufacturing Practices)

Course outline: Current at 22 Oct 2013

http://www.swinburne.edu.au/lss/postgraduate/good-manufacturing-practices.html

Duration: 6 months full-time/1 year part-time

Content: 3 core units plus one elective

Group A (Core)

International Good Manufacturing Practices and Quality Assurance (mandatory) Good Manufacturing Practices for Manufacturing Operations (mandatory)

One of the following units is mandatory:

Validation Principles

Good Quality Control Laboratory Practices

Contamination Control

Group B (Process Development Units)

A Perspective for Protein Therapeutics

A Perspective for Small Molecules

A Perspective for Medical Devices

Perspective for Pharmaceutical Finished Dose Forms

Group C (GMP Electives) Validation Practices

Good Laboratory Practices (for Non-Clinical Laboratories)

Computer Systems Validation Principles

Computer Systems Validation Practices

Good Aseptic Practices and Sterile Products

Clinical Trials Quality Assurance Management

GxP and Quality Auditing Practices

Research Skills

Group D (Electives)

Chemical Analysis of Pharmaceuticals

Environmental Testing and Water Science

Fundamentals of Process Analytical Technology

Chemometrics

Design of Experiments

Risk Management for Pharmaceutical Operations

Environmental Management

The Microbial World Microbes in the Environment

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Appendix B: The University of Manchester, Pharmaceutical Industrial Advanced Training (PIAT) MSC/PG Dip

Course outline: Current at 22 Oct 2013

http://www.mhs.manchester.ac.uk/postgraduate/

Duration: Up to 60 mths

Modules for the course are grouped under the following main themes:

- Industrial pharmacy
- Clinical trials
- Pharmaceutical Business Development and Licensing
- Pharmaceutical Microbiology

Industrial Pharmacy

1. Basic principles: The physicochemical principles of dosage form design
2. Preformulation studies 1
3. Preformulation studies 2
4. Oral Solid Dosage forms 1
5. Liquid and semi-solid dosage forms: Formulation and process development
6. Management Tools
7. Oral Solid Dosage forms 2
8. Lean Processes Introducing 6 Stigma
9. Quality control and quality assurance: Concepts, international regulatory requirements and management
10. Packaging: Materials, methods, regulatory requirements and product development
11. Regulatory affairs: International requirements in development, manufacturing and marketing*
12. Pharmaceutical engineering: An introduction to design, construction and operation of facilities
13. Quality control laboratory testing: Laboratory testing of raw materials and finished products
14. Safety, health and environment: Concepts, legislation and management*
15. Inhalation dosage forms: Formulation and process development
16. Product development management: An overview of the processes and management*
17. Scientific and medical writing*

*Assessed by assignments only (no written examination)

Clinical Trials

- Introduction to clinical trials
- Setting up and running clinical trials
- Phase I
- Phase II
- Phase III global clinical trials
- Statistical requirements and study design
- Pharmacovigilance
- Regulatory issues

Pharmaceutical Business Development and Licensing (All 8 modules in this category are assessed by assignments only - no written examination)

- Introduction to the healthcare industry
- Business development Operations
- Financial aspects of business development and licensing
- Legal issues in business development contracts
- Negotiation and interpersonal skills
- Marketing and commercialisation
- Intellectual property rights
- Research and development and manufacturing

Pharmaceutical Microbiology

- Introduction to pharmaceutical microbiology and technology
- Water aspects
- Microbiological environmental monitoring and control (sterile and non-sterile manufacturing areas)
- Microbiological aspects of sterile pharmaceutical manufacturing
- Quality assurance in microbiology laboratories
- Engineering principles for pharmaceutical microbiologists
- Application of microbiology in biopharmaceuticals
- Antimicrobials

Appendix C: NSF / University of Strathclyde, Ongoing and graduate certification in GMP

Modules offered: Current at 22 Oct 2013

http://nsf-dba.com/pages/qp-training

Duration: Course duration range from 1-5 days

Module 1 Pharmaceutical Law & Administration

Module 2 Medicinal Chemistry & Therapeutics

Module 3a Pharmaceutical Formulation & Processing, Part 1

Module 3b Pharmaceutical Formulation & Processing, Part 2

Module 4 Pharmaceutical Microbiology

Module 5 Active Pharmaceutical Ingredients

Module 6 Mathematics & Statistics

Module 7 Analysis & Testing

Module 8 Pharmaceutical Packaging

Module 9 Quality Management Systems

Module 10 Practical Module

Module 11 Investigational Medicinal Products

Module 12 The Role & Professional Duties of the QP

Appendix D: University College Cork, Masters Sc Pharmaceutical Technology and Quality systems

Course outline: Current at 22 Oct 2013

http://www.ucc.ie/en/ckx05/

Duration: 2 yrs full-time

Part I

PF6200 Pharmaceutical Chemistry (10 credits)

PF6201 Pharmaceutical Dosage Form Design (5 credits)

PF6202 Pharmaceutical Manufacturing - API to Finished Product (5 credits) PF6203 Pharmaceutical Microbiology and Sterile Manufacturing (5 credits)

PF6204 Biopharmaceutical Development of Investigational Medicinal Products (5 credits) PF6205 Pharmaceutical Biotechnology (5 credits)

PF6206 Pharmaceutical Statistics and Process Control (5 credits)

PF6207 Pharmaceutical Plant and Process: From Design through Validation (5 credits) PF6208 Quality Management Systems and Regulatory Affairs (5 credits)

PF6209 Role and Professional Duties of the Qualified Person (5 credits) PT6401 Pharmacology (5 credits)

Part II

PF6210 Research Project - Pharmaceutical Technology and Quality Systems (30 credits)

The research project will be centred in an industrial pharmaceutical setting. Consideration will be taken of the candidate's chosen project area but all project titles must be approved in advance by the programme committee and supervised by a member of academic staff at UCC.

Appendix E: Sligo Institute of Technology, Masters Science in Industrial Pharmaceutical Science

Course outline: Current at 22 Oct 2013

http://odl.itsligo.ie/science/bio-pharmaceutical-courses/m-sc-in-industrial-pharmaceutical-science/

Duration: 2 years

The programme is organised around a two-year cycle, during which 12 modules are studied and a research project will be carried out. Each year is split into two semesters and three modules are delivered in parallel during each semester.

The individual modules and their numbers are as follows:

1. Active Pharmaceutical Ingredients
2. Pharmaceutical microbiology
3. Processes and production
4. Project management
5. Medicinal chemistry
6. Pharmaceutical law, ethics and administration
7. Formulation
8. Quality systems
9. Biopharmaceuticals and Biopharmaceutical Analytical Techniques
10. Investigational Medicinal Products
11. Pharmacology and toxicology
12. Operations management

The programme provides teaching in 22 individual subject areas. These are addressed within individual modules as shown below.

Appendix F: Sligo Institute of Technology, BSc (Hons) in Pharmaceutical Science with Drug Development

Course outline: Current at 22 Oct 2013

http://courses.itsligo.ie/school-of-science/pharmaceutical-science/bsc-hons-in-pharmaceutical-science-with-drug-development/

Duration: 4 years

This four year honours degree course provides students with a broad but thorough background in the chemical, biological and technological disciplines as they relate to the study of medicinal products.

Pharmaceutical science covers a wide range of topics including all aspects of the development, manufacture and study of medicinal compounds. It provides excellent training in scientific principles, practical applications, organisational and computing skills, as well as self-discipline.

In addition to the main science subjects, other modules that you will study include:

- dosage formulation
- biopharmaceuticals
- pharmaceutical manufacturing
- quality systems
- validation
- pharmaceutical legislation.

As a graduate you will be multi-skilled and will typically gain employment throughout the pharmaceutical/healthcare industrial sector. Should you wish to progress your studies, you will be well equipped to pursue higher degrees such as MSc or PhD.

PharmOut is an international GMP consultancy serving the Pharmaceutical, Medical Device and Veterinary industries. PharmOut specialises in PIC/S, WHO, United States FDA, European EMA, and Australian TGA GMP consulting, engineering, project management, training, validation, continuous improvement and regulatory services.

Our team includes international GMP experts who have previously held leadership roles within regulatory bodies.

For more information please visit www.pharmout.net or contact us at info@pharmout.net.

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