



# Implementation of Effective GMP Training and Development Programs for Manufacturing and Technical Staff

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# Overview

- GMP requirements (similar for RMP/FSP and cosmetics)
- Needs analysis
- Planning and resourcing
- NZ industry training landscape
- Summary points





# GMP and Training



- GMP is about following **procedures** and **written instructions**
- Demonstrates consistency and compliance through **complete records**
- Only **trained** and **competent personnel** whose records have been signed should work in a GMP facility



# Training needs



- Knowledge of applicable GMP requirements
- Understand company procedures
- Competent at tasks required
- Understand and demonstrate correct use of records
- Reporting of deviations/incidents
- Understand the process and impact of change
- Completed training records



# Training levels



- Induction = move within the factory GMPs, personnel and product safety
- Contractors/visitors (consider intrusive roles)
- Knowledge of GMP procedures
- Qualifications/work experience (awareness)
- Skills = operate, conduct process (well) [Competency]
- Development or improvement framework
- Ability to assess and/or train others



# Training needs assessment

- What education/qualification is required
- What knowledge is desirable
- Level of competency/awareness
- Level of competency/execution
- Applicable standards
- Refresher requirements
- Assessment/maintenance
- Development needs



# Company needs assessment

## SWOT ANALYSIS

	Helpful to achieving the objective	Harmful to achieving the objective
Internal origin (attributes of the organization)	<b>S</b> Strengths	<b>W</b> Weaknesses
External origin (attributes of the environment)	<b>O</b> Opportunities	<b>T</b> Threats



**Strengths**  
Think about the skills and experience you currently hold.  
*What have you achieved?  
What are you good at?  
What are your skills?*

**Weaknesses**  
Think about the skills and experience that you don't currently hold but require.  
*Do you lack any skills/qualifications?  
What professional qualities do you need that you don't currently have?*

**Opportunities**  
Think about what the future holds and what opportunities will there be for you.  
*What is happening in your environment that will provide an opportunity for you to develop new skills?  
What opportunities will provide you with new experiences?*

**Threats**  
Threats are those factors that are affecting your environment and which may mean new skills or experience is required.  
*What is happening in your environment that may require new skills?  
What is happening with your role that may require new skills?*





# Role based training needs - knowledge

SOP No.	Subject	Quality Representative	Manager / Supervisor	Production Operator	
001	Quality Management	✓	✓	Read	
002	Quality Risk Management	✓	✓		
003	Document Management	✓	✓	✓	
004	Human Resources	✓	✓		
005	Training	✓	✓	✓	
006	Change Management	✓	✓	Read	
007	Deviations, Non-conformance and CAPA	✓	✓	✓	
008	Out of Specification (OOS) Investigations	✓	Read		
009	Internal Quality Audits (IQA)	✓	Read	Read	
010	Supplier Evaluation, Approval and Audit	✓	✓		
011	Third Party Agreements	✓	✓		
012	Purchasing	✓	✓	Read	
013	Status Labelling	✓	Read	✓	
014	Inwards Goods Receipts, Quarantine and Release	✓	As applicable	As applicable	
015	Retention Samples	✓	Read	✓	
016	Printed Packaging Management	✓	As applicable	✓	
017	Use of Computers	✓	✓	✓	
018	Management of Validation	✓	✓		
019	Batch Numbering and Expiry/Retest Dating	✓	As applicable	✓	



# Role based training needs - competency

Ref No.	Subject	Quality Representative	Manager	Production Supervisor	Production Operator	Laboratory Technician	Engineer	Contractor
001	Gowning	2	1	2,3	2, 3	2	2, 3	2
002	Raise/report a deviation	3	1	2,3	1-3	1-3	1, 2	1
003	Perform dispensing	R1	R2	3	2, 3	N/A	R2	N/A
004	Receipt a product into the store	R2	R1	3	R1	R1	R2	N/A
005	Operate a powder filler	R1	R2	3	2, 3	N/A	1,2	R1
006	Clean a powder filler	R1	R2	3	2,3	R1	1	R1
007	Set up a bottle filling line	R1	R1	R2	R2	N/A	2,3	2
008	Conduct a release test	3	N/A	N/A	N/A	2, 3	N/A	N/A
009	Check a line/room clearance	R2	R1	3	2	R2	R1	R1
010	Perform an audit	3	R1	2	R2	2	1	N/A
011	Assess a supplier	3	R2	R2	N/A	R2	2	N/A
012	Calibrate an instrument	R2	N/A	R2	R1	2	3	2, 3
013	Pick product for despatch to customer	R2	R1	2	2, 3	N/A	N/A	N/A
014	Sample environment for microbial contaminants	R2	N/A	2	R1	1- 3	N/A	N/A
015	Conduct a product recall	3	2	1	N/A	N/A	N/A	N/A

Training Level: R =Read/understand (1 = aware or 2 = knowledgeable), 1 = able to work under supervision, 2 = able to work without supervision, 3 = able to train others



# Role based training needs - records

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## TRAINING RECORD – TASK BASED

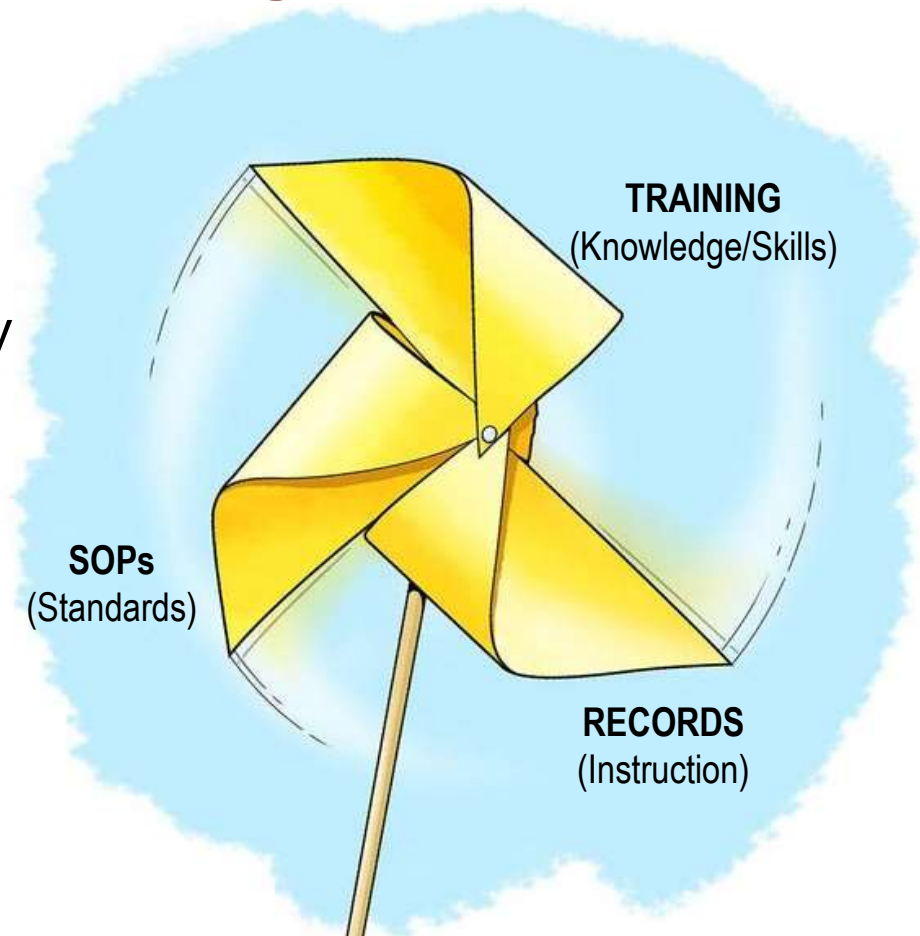
Name:

Sheet No.: \_\_\_\_\_

Training Procedure/Task	Date commenced	Level 1			Level 2			Level 3		
		Date completed	Trainee	Trainer	Date completed	Trainee	Trainer	Date completed	Trainee	Trainer

# Planning - a balancing act...

- What must be stated for traceability and compliance
- What instructions are necessary and what supporting role should they play
- What knowledge should be reasonably expected to be retained





# Training and performance



## GMP and other regulations do not deliver quality.

- Staff need to be capable and motivated to deliver quality
- Motivation comes (deliberately or otherwise) from the culture and management of the company...
- Behaviors are a barometer of motivation and culture
- Behavior is a consequence of the way staff are trained, managed and measured.



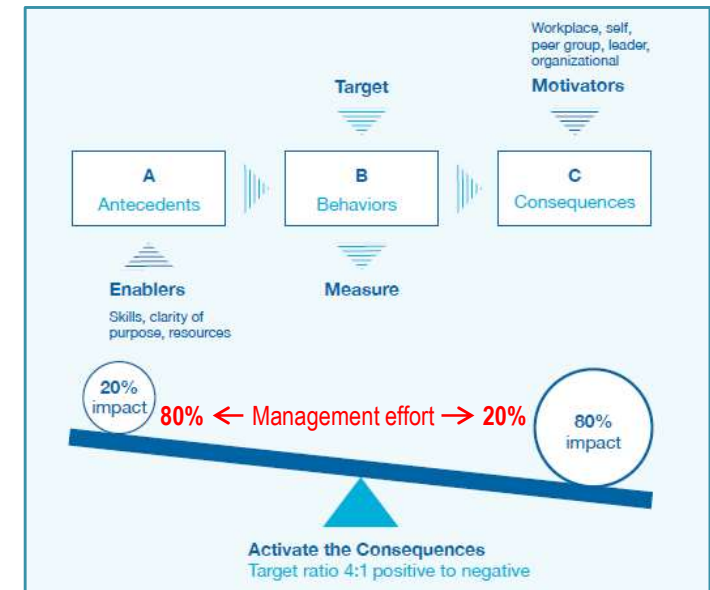
# Training and performance



## Activate the Consequences

### ABCs of Behavioural Science

- Develop training plans focussed on desirable behaviours, not just compliance
- Measure (encourage) desirable behaviours to assess training effectiveness
- Consequences are 4X more effective than antecedents (training, SOPs and instructions) for delivering desired quality/performance





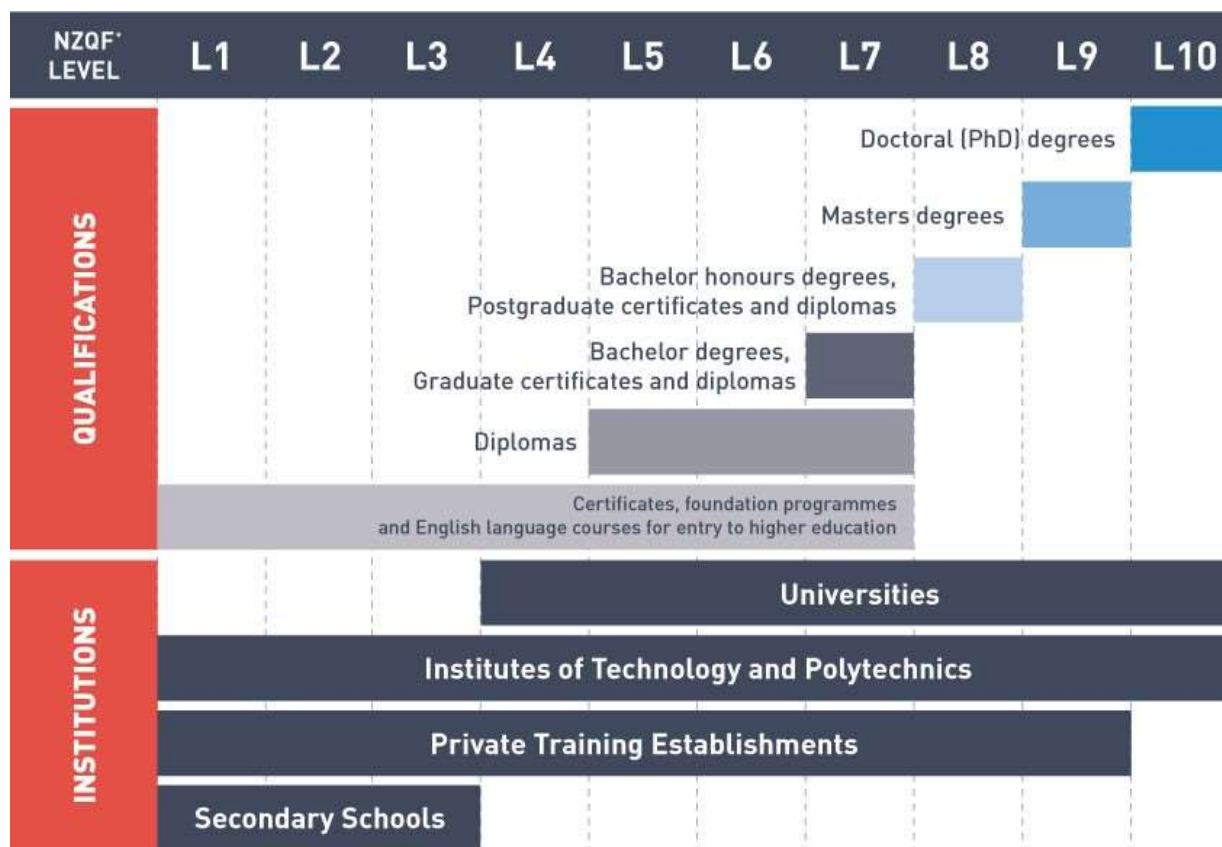
# Training Delivery



- Education = University (pharmacy, science, engineering, bioprocessing, laboratory)
- Education/experiential = Polytech/tertiary, PTEs (food science, laboratory, engineering)
- Commercial training providers (industry knowledge and rules)
- OJT (On the job training)
- Self-run programs



# NZ Qualifications Framework




\* NZQF = New Zealand Qualifications Framework determined by NZQA

Studywise NZ



# NZ Qualifications Framework

<b>Master of Drug Discovery and Development</b> Victoria University of Wellington University DURATION: 1.5 Years NZQF LEVEL: 9 ... knowledge of the processes and activities involved with drug discovery, design and development in the <b>pharmaceutical</b> , nutraceutical, agricultural, bioanalytical, chemical and related industries. Graduates will be equipped to conduct independent ...	<b>Postgraduate Certificate in Pharmacy</b> University of Otago University DURATION: Less than one year NZQF LEVEL: 8 Graduates of this certificate programme will be able to undertake further advanced-level study or research in the <b>pharmaceutical</b> sciences, clinical pharmacy, or pharmacy practice.	<b>Postgraduate Diploma in Clinical Pharmacy</b> University of Auckland University DURATION: 1 year NZQF LEVEL: 8 Pharmacists who complete the PGDipClnPharm will have greater experience in the preparation and implementation of <b>pharmaceutical</b> care and medicines management plans for a wide range of therapeutic areas, and for ...
<b>Postgraduate Certificate in Clinical Pharmacy</b> University of Auckland University DURATION: Less than one year NZQF LEVEL: 8 Pharmacists who complete the PGCertClnPharm will be able to develop <b>pharmaceutical</b> care plans for individual patients in selected therapeutic areas, and to consider issues associated with the implementation of such ...	<b>Postgraduate Certificate in Drug Discovery and Development</b> Victoria University of Wellington University DURATION: 21 Weeks NZQF LEVEL: 8 Graduates will be able to apply selected knowledge of chemical biology and drug discovery to the <b>pharmaceutical</b> , nutraceutical, agricultural, bioanalytical, chemical and related industries. Graduates may be able to continue ...	<b>Bachelor of Engineering with Honours</b> University of Canterbury University DURATION: 4 years NZQF LEVEL: 8 Engineers design the future. They provide innovative solutions to meet the needs of our modern world. From buildings and bridges, to apps and smart devices, to <b>pharmaceuticals</b> and renewable energy ...
<b>Postgraduate Diploma in Drug Discovery and Development</b> Victoria University of Wellington University DURATION: 1 Year NZQF LEVEL: 8 ... knowledge of the processes and activities involved with drug discovery, design and development in the <b>pharmaceutical</b> , nutraceutical, agricultural, bioanalytical, chemical and related industries. Graduates will be able to interpret research ...	<b>Bachelor of Pharmacy</b> University of Auckland University DURATION: 4 years NZQF LEVEL: 7 ... as understanding how drugs are developed, patient use, and pharmacists optimising patient care through interaction with other health professionals. Themes in population medicine, social science, pharmacology, pharmacy practice and <b>pharmaceutic</b>	



NEW ZEALAND QUALIFICATIONS AUTHORITY  
PANA TŌHŪ MĀTAURANGA O AOTIAROA  
QUALIFY FOR THE FUTURE WORLD  
KIA MŌHIO TAKATO KI TŌ AHAU AHO

Ka te manu ka hoi i te mōro, nōna te ngahere. Ka te manu ka hoi i te mōkauranga, nōna te ao.  
The bird that portends of the berry, stays in the forest. The bird that portends of knowledge, stays in the world.  
(Te Kōwhiri, Te Kōwhiri o Te Kōwhiri)

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## Qualification Overview

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1	Qualification Title	National Certificate in Pharmaceutical and Allied Products Manufacturing (Level 1)
2	Qualification Type	National Certificate
3	Level	1
4	Credits	40
5	Subject Area	<ul style="list-style-type: none"> <li>Engineering and Related Technologies » Manufacturing, Engineering and Technology » Manufacturing Engineering and Technology not elsewhere classified</li> <li>Manufacturing » Pharmaceutical and Allied Products » Pharmaceutical and Allied Products Manufacturing</li> </ul>
6	Strategic Purpose Statement	<p>The National Certificate in Pharmaceutical and Allied Products Manufacturing (Level 1) [Ref: 1233] is an introductory qualification intended to provide foundation skills for employees involved in activities related to the manufacture of pharmaceutical and allied products. Holders of this certificate are able to work under supervision, in a range of roles associated with pharmaceutical and allied products manufacturing. These roles include dispensing, manufacturing, packing, quality control and warehousing.</p> <p>The qualification provides a core of compulsory skills and knowledge associated with the compliance requirements for Good Manufacturing Practice as defined in relevant legislation and regulations, as well as an introduction to the manufacturing systems and procedures used by the industry. It also comprises fundamental health and safety, communications, and numeracy skills. The elective section of the qualification is designed to meet individual industry preferences, as well as providing a foundation for the various options available for higher qualifications.</p> <p>Certificate holders are encouraged to undertake further training towards the National Certificate in Pharmaceutical and Allied Products Manufacturing (Level 2) [Ref: 1234]. Alternatively, certificate holders who wish to specialise in the engineering related activities required by this sector, can train towards the National Certificate in Engineering and Technology (Pharmaceutical and Allied Products) (Level 2) [Ref: 1235]. This certificate is a prerequisite for both of the above National Certificates. <a href="#">[collapse]</a></p>
7	Entry Requirements	Not available
8	Developed By	 Te Pūkenga WBL Ltd. T/A Competenz
9	Quality Assured by	New Zealand Qualifications Authority
10	Number	1233
11	Status	Discontinued
12	Created	March 2006
13	Next Review	December 2010
14	Discontinued	November 2015



# Other providers





# Key Points

- Training is required to maintain an effective and compliant workforce
- Effective training involves a combination of knowledge, skill and competency and must be maintained
- In order to properly assess training needs an organization must consider the levels of competency required across the operation and applicable standards for this
- A properly trained and motivated workforce will deliver performance and quality benefits beyond compliance and GMP requirements
- Training provides awareness of standards and enables achievement; however should be focused on encouraging desirable behaviours
- Highly effective training and development can will deliver positive or desirable consequences which should sustain desired outcomes
- It is helpful to understand the role of tertiary training providers; however they are unlikely to offer industry skills-based training. They can play a role in workforce knowledge and development
- Industry must identify skill shortage areas and will need to work collaboratively or individually to build capability in these areas – particularly for technical competency.