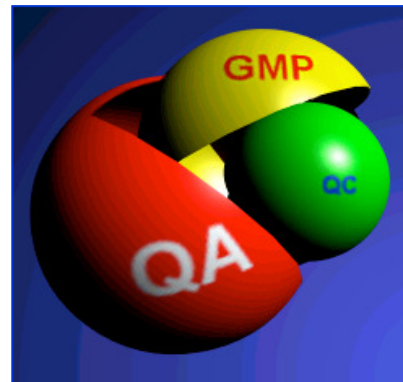


SeerPharma Pty Ltd

SeerPharma (Singapore) Pte Ltd



10 Anson Road, #35-09 International Plaza, Singapore 079903

Darren Freestone
www.seerpharma.com

Cosmetics

- ★ What does *being regulated* mean?
- ★ What exactly is **GMP** for Cosmetics?
- ★ What about other markets *outside* Singapore?
- How do GMP and PIF relate?

Is it Confusing?

CODES

GUIDELINES

ISO STANDARDS

NATIONAL STANDARDS

PRODUCT INFORMATION FILES (PIF)

What is the Requirement in Singapore?

GUIDELINES ON THE CONTROL OF COSMETIC PRODUCTS

SPECIFIC FOR SINGAPORE

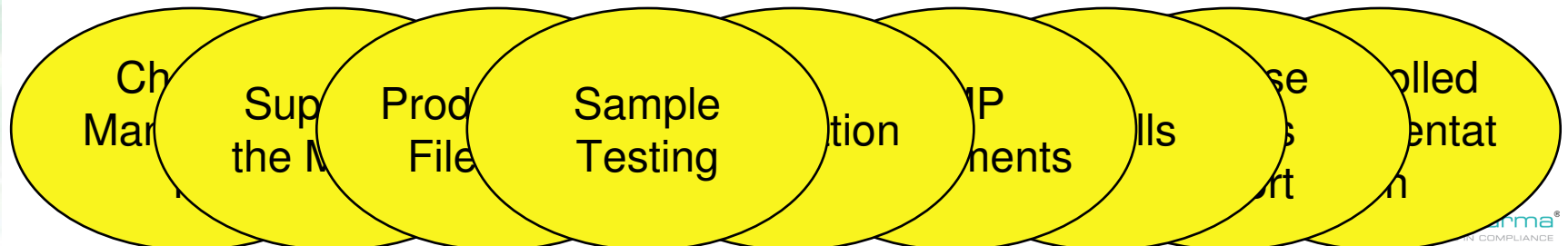
Medicines (CP)
(Specification and Prohibition) Order and its amendment
Medicines (CP)
(Licensing) Regulations
Medicines (CP)
(Labelling) Regulations
1996
Medicines (GMP Certificate - CP)

HSA
REQUIREMEN
T

What do we need?



GUIDELINES ON THE CONTROL OF COSMETIC PRODUCTS



GUIDELINES ON THE CONTROL OF COSMETIC PRODUCTS

Controlled
Documentation

Written
PROCEDURES

Define your documents (eg)

- * Procedures
- * Forms
- * Specifications
- * Formulations
- * Test Methods

How to create & revise
How to Issue & Control
How to maintain records

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GUIDELINES ON THE CONTROL OF COSMETIC PRODUCTS

Adverse
Events
Report

Written
PROCEDURE
S

- Describe actions to take (eg)
- * Responsibilities
 - * Definitions of AE
 - * Risk Management
 - * Escalation to Management
 - * Integration with Complaints
 - * Notification to HSA
 - * Timelines for Reporting
 - * Standard Templates
 - * Investigations
 - * Corrective Preventive Actns

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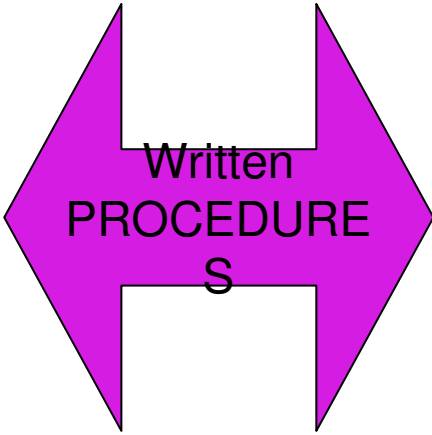
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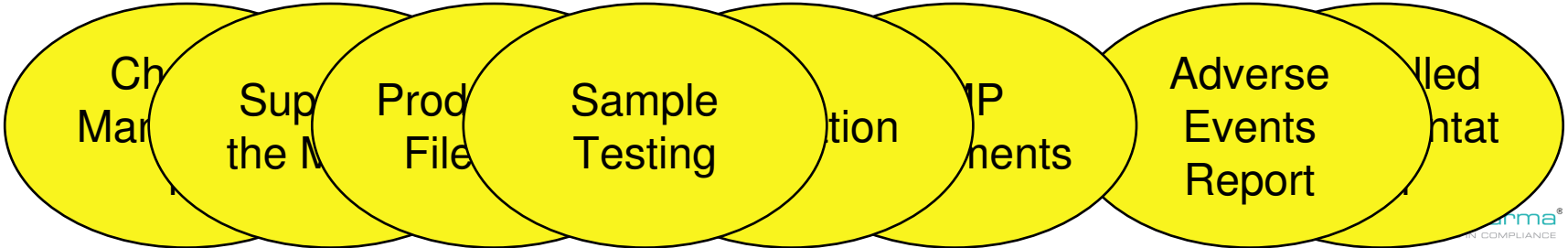
Controlled
documentat
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GUIDELINES ON THE CONTROL OF COSMETIC PRODUCTS

Recalls

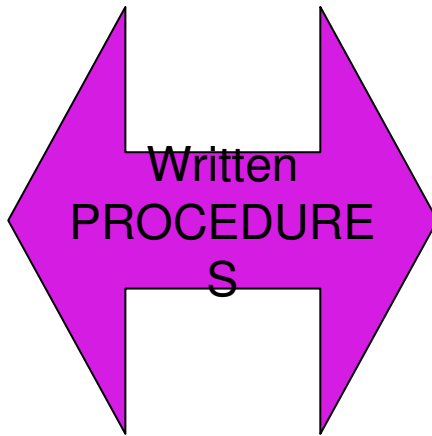


- Describe actions to take (eg)
- * Responsibilities
 - * Definitions
 - * Risk Management
 - * Escalation to Management
 - * Integration with Complaints
 - * Notification to HSA
 - * Timelines for Reporting
 - * Standard Templates
 - * Investigations
 - * Corrective Preventive Actns

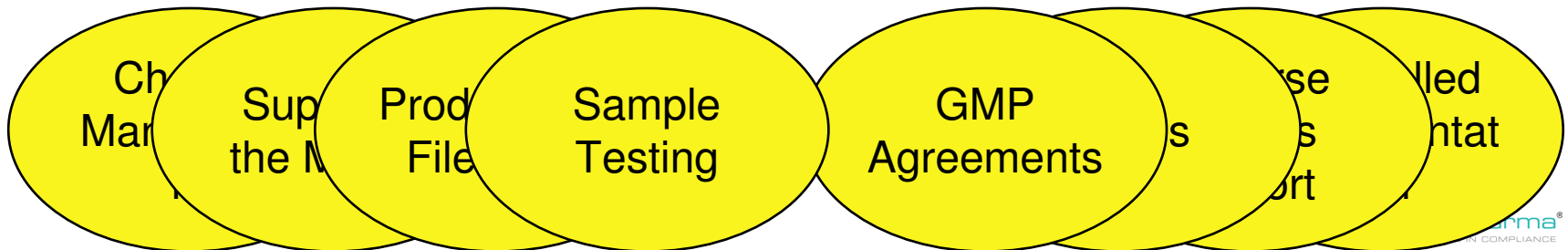


GUIDELINES ON THE CONTROL OF COSMETIC PRODUCTS

Notification



- Requirements HSA
- * Notification
 - * Re-notification
 - * Methodology
 - * Responsibilities
- Integration with Change Management

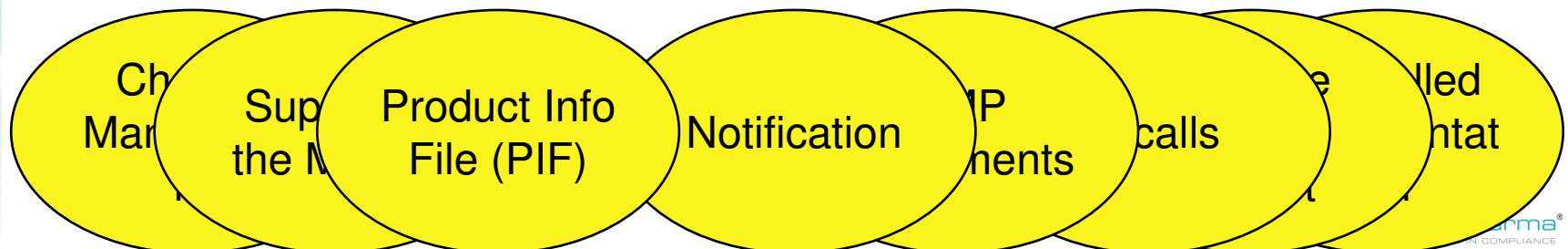
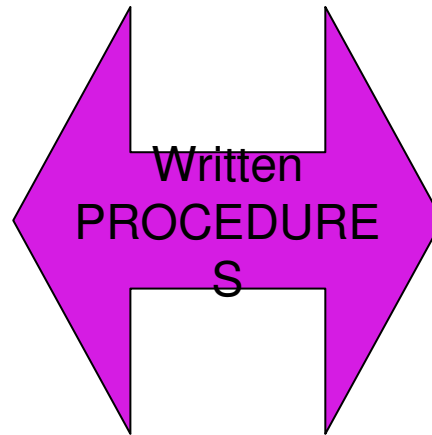


GUIDELINES ON THE CONTROL OF COSMETIC PRODUCTS

Requirements of the HSA

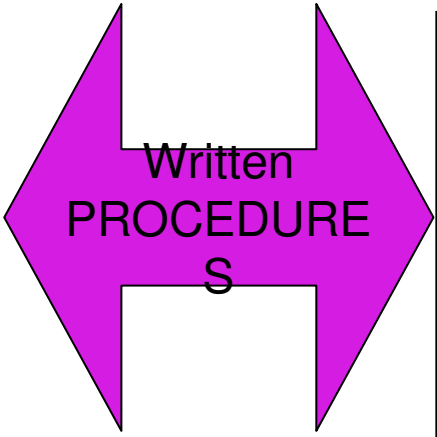
- Notification to management
- When to take a sample
- From where to take a sample
- How to take a sample
- How to label, transport & deliver
- Responsibilities
- How to pay

Sample Testing

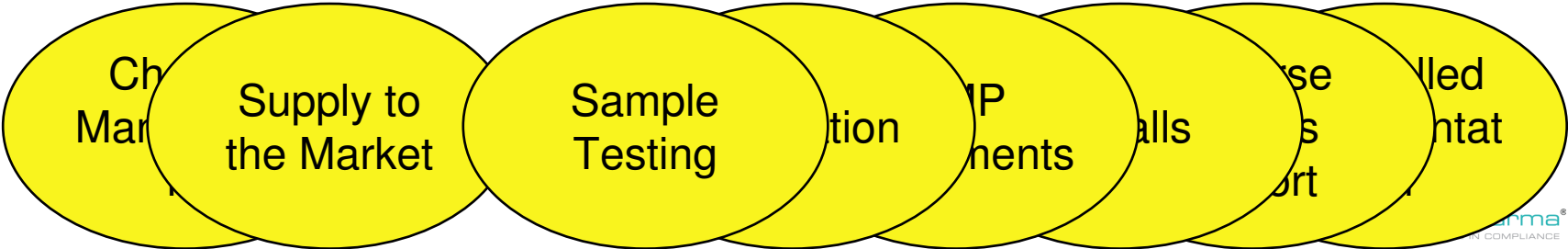


GUIDELINES ON THE CONTROL OF COSMETIC PRODUCTS

Product Info File (PIF)



- Requirements of the HSA
- Responsibilities
- Standard Template
- How to Prepare and Change
- How to Authorise
- How to Maintain



GUIDELINES ON THE CONTROL OF COSMETIC PRODUCTS

Change Management

Written PROCEDURE S

Define "changes" (eg)

- * Intended use
 - * Manufacturer
 - * Formulation
 - * Company representative
 - * Packaging Material
- Roles and Responsibilities
Integration with PIF
Approved Suppliers List
Notification to management
Risk Management

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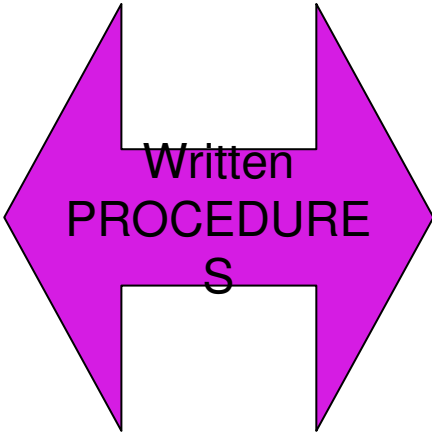
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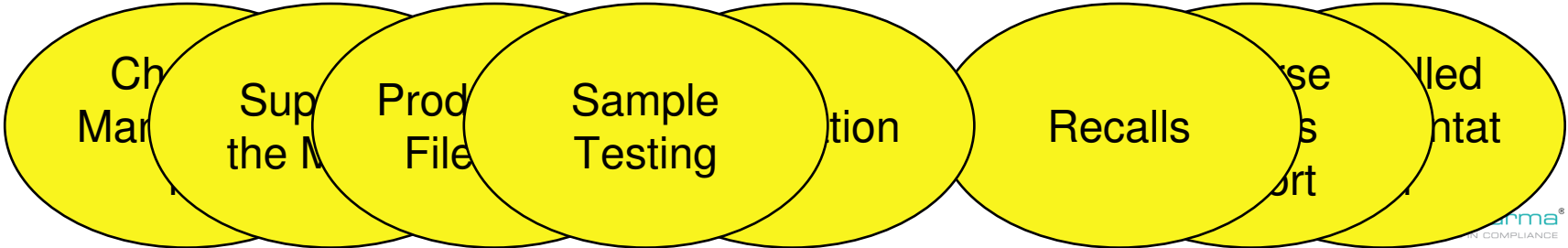
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GUIDELINES ON THE CONTROL OF COSMETIC PRODUCTS

GMP Agreements



Defines a GMP Agreement
Circumstances when needed
Roles and responsibilities
Standard Template
Review and Approval Authority
Maintenance





GMP - what is it?

Great **M**ountains of **P**aper

Grab-it
Make-it **P**ack-it

Good **M**anufacturing **P**ractices

GMP - what is it?



Good Manufacturing Practices



Good Manufacturing Practices

CODES

GUIDELINES

ISO STANDARDS

NATIONAL STANDARDS

Manufacturers must follow to make
their products
(Regulated Environment)

Examples:

ISO 22716 Cosmetics - Good Manufacturing Practices (GMP) - Guidelines on Good Manufacturing Practices

ASEAN Guidelines For Cosmetic Good Manufacturing Practices

Malaysia Cosmetic GMP Guidelines

Australian Code of Good Manufacturing Practice for Therapeutic Goods - Sunscreen Products

Cosmetic Good Manufacturing Practices, COLIPA - The European Cosmetic Toiletry and Perfumery Association, July 1994



Each country, will decide whether it will require a cosmetic product to be manufactured under the conditions of “GMP”

If “GMP” is required for the manufacturer, then the country will decide which code / guideline / standard to adopt as it’s minimum GMP requirements

For Example:

Japan
Europe

ISO 22716

Malaysia

Malaysia
GMP

Vietnam

ASEAN
GMP

For Singapore? Prior to 2 July 2010

A statement from the

- * manufacturer, or
- * company

That the cosmetic product was manufactured according to:



For Singapore? Post 2 July 2010



GMP Guidelines for Manufacturers of Cosmetic Products



For Singapore

This means that cosmetic products supplied in Singapore are required to be manufactured according to GMP

What about me?

Two Main Scenarios:

Cosmetics Company who do not actually manufacture the product

Cosmetics Company who also manufacture the product

What about me?

Cosmetics Company who do not actually manufacture the product

SOPs

PIF

GMP Agreement

Manufacturer Provides:

- * manufacturing process
- * raw material details
- * quality controls
- * test methods
- * stability information
- * test results
- * complaints (AE)
- * etc

What about me?

Cosmetics Company who also manufacture the product

SOPs

PIF

GMP Agreement

YOU Provide

- * manufacturing process
- * raw material details
- * quality controls
- * test methods
- * stability information
- * test results
- * complaints (AE)
- * etc

What about me?

Cosmetics Company who also manufacture the product

SOPs

PIF

GMP

YOU Provide

- * manufacturing process
- * raw material details
- * quality controls
- * test methods
- * stability information
- * test results
- * complaints (AE)
- * etc

GMP

Controlled Documentation
Adverse Events Reporting
Recall
GMP Agreements
Sample Testing
Supply to Market
Notification
Change Management

GMP

Controlled Documentation
Adverse Events Reporting
Recall
GMP Agreements
Sample Testing
Supply to Market
Notification to Authority
Change Management

Equipment
Installation
Equipment Status
Calibration
Risk Management
Supplier Qualification

SOME EXAMPLES OF TOPICS!

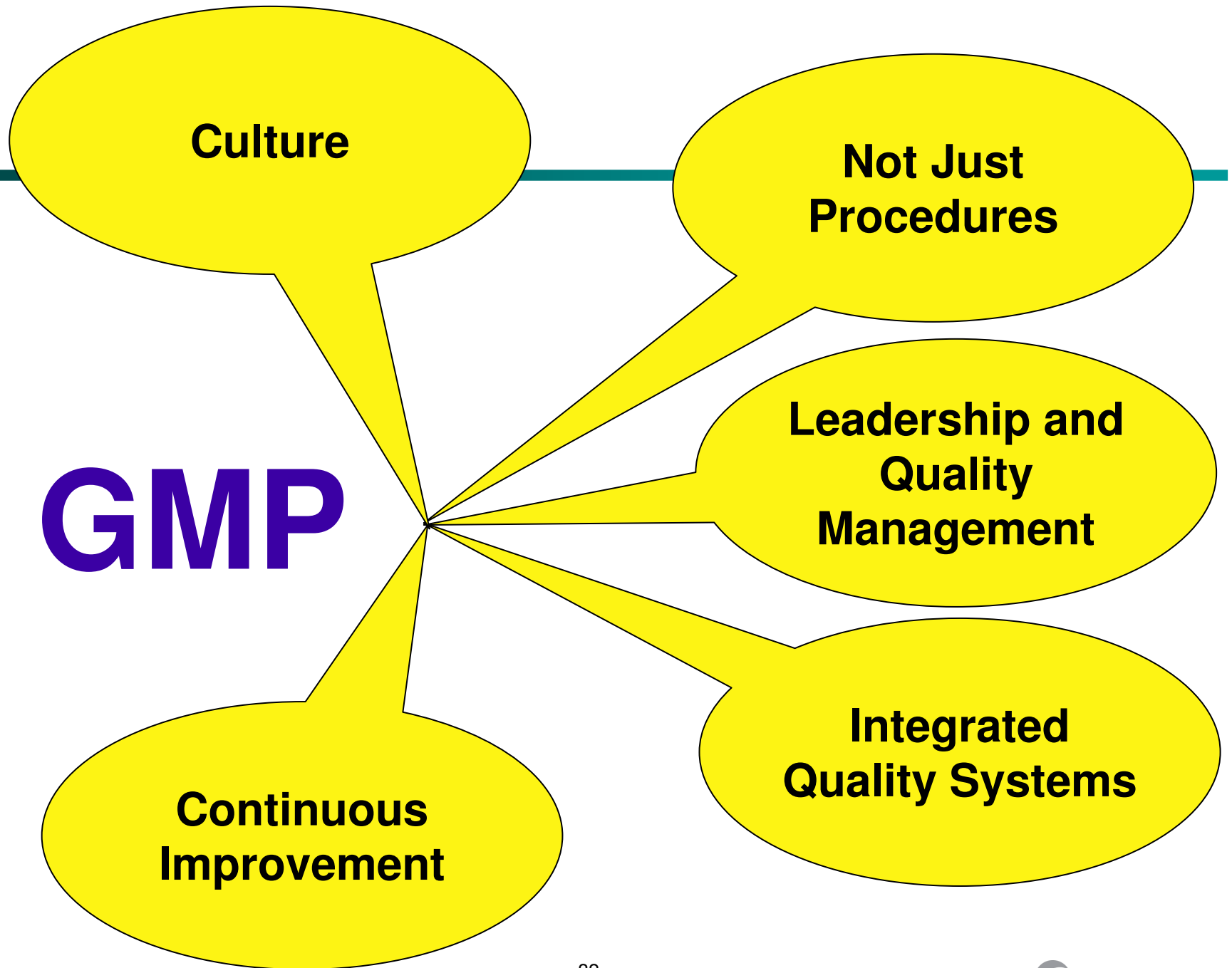
Personnel
Roles and Responsibilities
Training
Health and Hygiene
Premises
Cleaning and Sanitation
Maintenance
Complaints

GMP Agreements
Purchasing
Release for Supply
Production Controls
Manufacturing Operations
Packaging Operations
Storage and Handling
Sampling and Testing
Deviations Management
Out of Specification Management
Product Rework

GMP

It is not uncommon that a manufacturing facility could have 500+ Standard Operating Procedures!

Plus the FORMS
Plus the RECORDS
Plus.....
Plus.....





**HSA GMP Guidelines
for Manufacturers of
Cosmetic Products**

**Manufacturers must develop
their own internal QMS and
procedures....**



Thank you!!!