CIPS
Chartered Institute of Purchasing & Supply

How to Get What Purchasing Wants
in a Regulated Environment

Event Sponsors

Lime Associates
Medical Purchasing & Supply Solutions

Agenda

15.45	Event Registration
16.00	Event Start and Introduction (Lee Robinson & Malcolm Youngson)
16.15	Regulatory Impacts in the HT Industry (Mike Bullivant)
17.15	Break for Refreshments & Networking
17.45	How to make sure Purchasing Succeeds (Ed Luttrell)
18.45	Next Event Discussion (Paul Currah)
19.00	Event Close

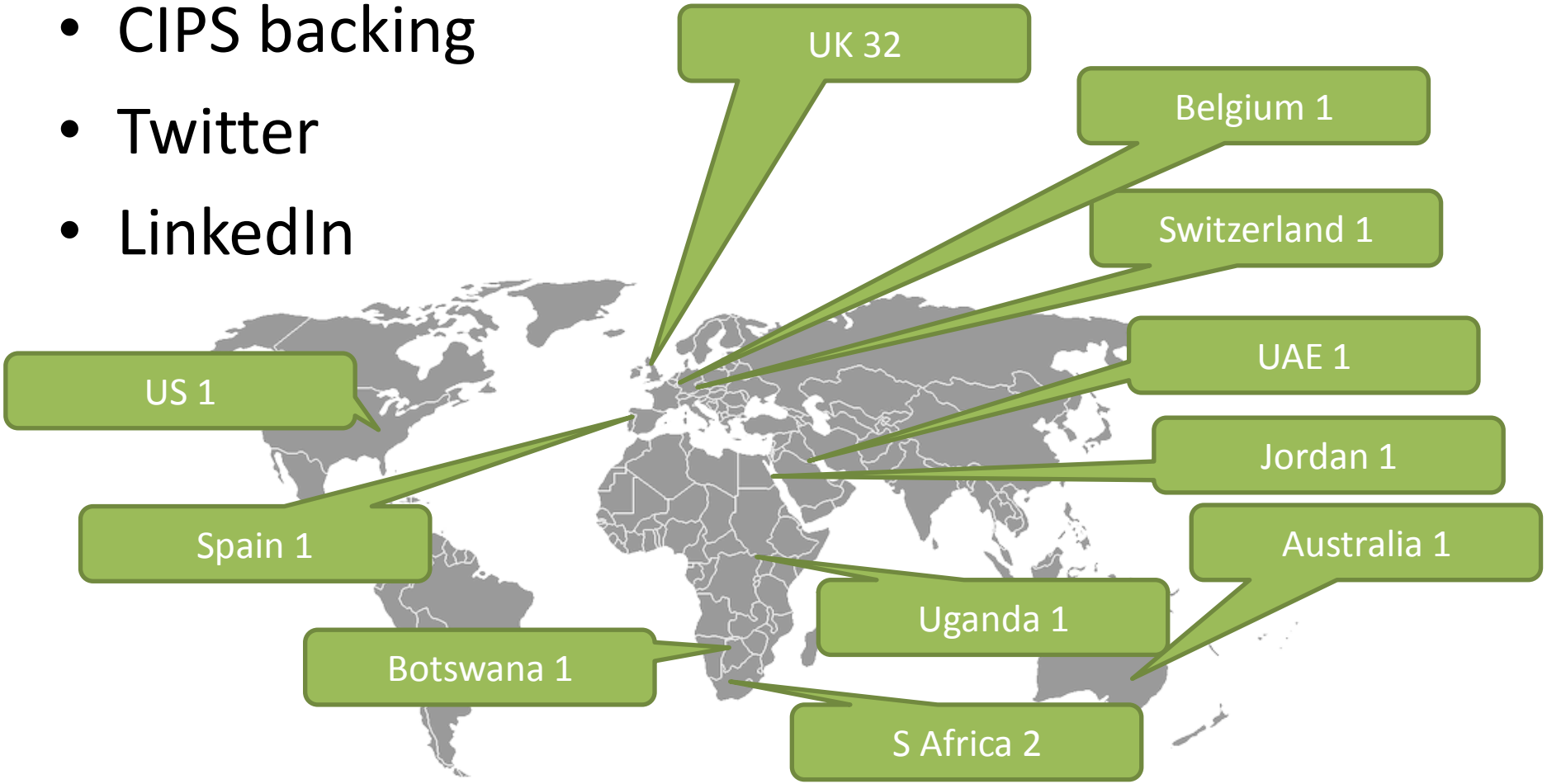
Lime Associates
Medical Purchasing & Supply Solutions

CIPS
Chartered Institute of Purchasing & Supply

Lime Associates
Medical Purchasing & Supply Solutions

CIPS HT Group

- 18 months in development
- CIPS backing
- Twitter
- LinkedIn



Lime Associates
Medical Purchasing & Supply Solutions

Inaugural Event

"The aim of the event is to provide members and non-members with an understanding of how challenging purchasing within Health Technology is, and more importantly to leave with a real understanding of how they can have an impact within their own organisations."

Malcolm Youngson
CIPS

Mike Bullivant

A History of Medical Device Quality Management System & Regulatory Requirements

Incarnation of the Board of Health 1805

Ministry of Health created 1919

NHS establishment within the MoH in 1945

Before the MHRA

MDA certificated the COMPANY to manufacture devices together with the approval to use the device by a Clinician

Devices manufactured under a Quality Management System (QMS) BS 5750 & later BS 9000
& now ISO 13485

Medicines Control Agency (MCA) & Medical Devices Agency (MDA) merged to form Medicines & Healthcare products Regulatory Agency (MHRA) in 2003

AFTER THE FORMATION OF THE M.H.R.A .

A STEP CHANGE

The CE marking of Medical Devices as it is legally called since 1993 (per Directive 93/43/EEC) CE mark is a mandatory conformity mark for products placed on the market in the European Economic Area(EEA).

With the CE marking on a product the manufacturer ensures that the product conforms with the essential requirements of the applicable EC directives.

BS EN ISO 13485:2003
QMS
&
Medical Device Directives

This QMS was introduced specifically for Medical Device manufactures and replace ISO 9000 QMS

MDD 93/42/EEC introduced as a way of CE marking Devices

MHRA appoint Notified Bodies to :-

a) Approve manufactures Technical Files

b) Approve their QMS

Prior to the issue of the CE Mark on the Medical Device concerned

Aim of Quality Management System

Aim of Quality Management System

- The basic goal of quality management is the elimination of failure:

Aim of Quality Management System

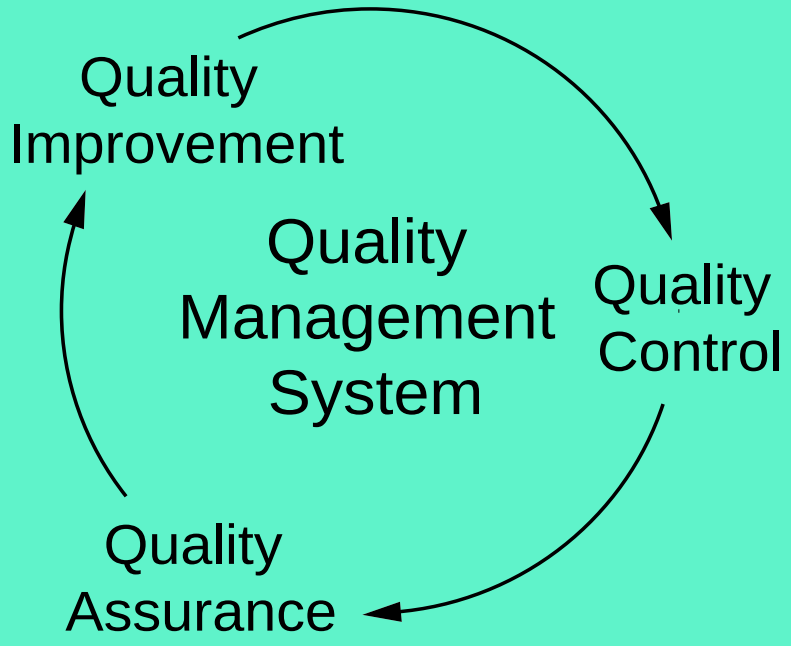
- The basic goal of quality management is the elimination of failure:

- Both in the concept and in the reality of our products, services and procedures.

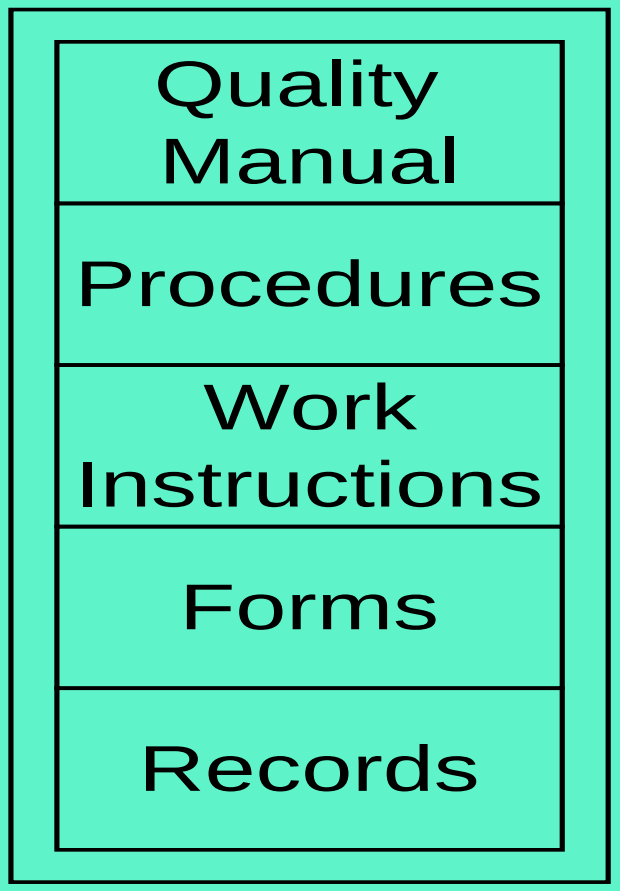
Aim of Quality Management System

- The basic goal of quality management is the elimination of failure:

- Both in the concept and in the reality of our products, services and procedures.



Design of the QMS

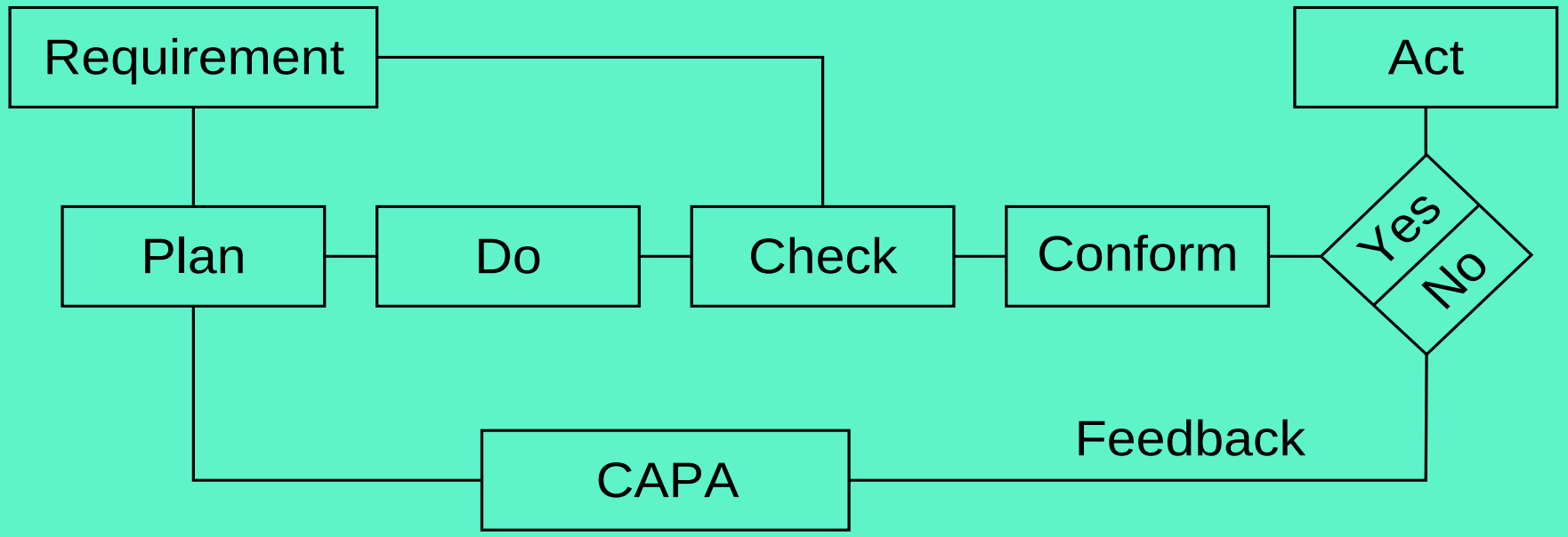


The QMS consists of:

- Quality Manual top level system
- Procedures for each operation
- Work Instructions for the operator
- Forms to record information
- Records to prove activities

Quality Control

- Quality control is the operational techniques and activities that are used to fulfil requirements for quality.



Standards Operating Procedure (SOP)

Quay Side Parking SOP

Drive to the edge of the water and leave your car.

YOU MEAN LIKE THIS ?

Quality Improvement

- Quality improvement is the process by which Quality Control is constantly updated to maintain effective delivery right through to the customer.

Quality Assurance

- Quality Assurance is a method of ensuring adequate confidence that the requirement of Quality will be met.
- Quality Assurance establishes the extent to which quality will be, or is being controlled.

Quality Goals

- Quality goals may be derived from a wide range of actions; such actions include:
  - establish customer needs
  - customer satisfaction
  - design of products and services with features that reflect customer needs
  - prevent supplying products that posses features that dissatisfy customers

Quality Management System (QMS)

- Purpose –
  - to enable an organisation to achieve, sustain and improve quality cost effectively.
- Requirements:
  - robustness
  - maintainability
  - reliability
  - flexibility
  - consistency
  - compliance
  - usability
  - traceability

Why Do We Have Quality?

- Our company is commitment to quality and achievement of ISO certification
- Our certification is awarded because we demonstrate consistently that we have documented procedure and that we adhere to them.
- Continuous improvement to identify problem areas and address them before they impact our business.

Surveillance Visits

- Who is our Notified Body
  - BSI or LRQA or SGS !!!!!!!!!!!!!!!!!!!!!!!!!!!!
- How do they ensure we comply to the requirements
  - They perform Six Or Twelve month surveillance visits
- These audits are made to Ensure we:
  - say what we do
  - ….and do what we say

Who / What

- What is covered by the QMS
  - Every department within the company
- Who is responsible for quality ?
- Everyone!!
  - We all can have an impact on the quality of our product and services

What Do You Need to Do?

- Familiarise yourselves with the QMS.
- Use the correct version of the forms, procedures and work instructions.
- Communicate any changes to your working procedures.
- Make sure we capture all customer feedback - POSITIVE & NEGATIVE

Internal Auditing

- The purpose of auditing is to detect and correct any non conformances.
- Non conformances are defined as discrepancy between actual feature and specified requirement.
  - (e.g. procedure is correct, but not followed, or procedure is at fault).

What Do You Get from the QMS

- Key things you need to know about "YOUR CUSTOMER"
- Consistency means customer satisfaction.
- You do NOT need to re-create the wheel or re-create the standards. But……you can always contribute to their improvement

Continuous Improvement

- We want to continue listening and learning from each other and from our customers so we can develop a system that works for us.
- A system that will give our customers a greater consistency and satisfaction.
- Allowing our Sales Specialists to perform tasks without being restricted.
- There will be ongoing training on QMS.

Conclusion

- Lets Get It "Right First Time"
- Make sure we capture all feedback - POSITIVE & NEGATIVE
- Always ask the question:-

Do we:

  - say what we do?
  - ….and do what we say?

- If the procedure needs amending to improve it, then lets change it!!

European Directives

1 Council Directive 93/42/EEC Concerning Medical Devices

1. **Council Directive 93/42/EEC Concerning Medical Devices**
2. **Council Directive 98/79/EEC In Vitro Medical Devices**

1. **Council Directive 93/42/EEC Concerning Medical Devices**
2. **Council Directive 98/79/EEC In Vitro Medical Devices**
3. **Council Directive 90/385/EEC Active Implantable Medical Devices**

1

23 Artilcle statements.

2

12 Annex Sections

1

Annex I - Essential Requirements

2

Annex I - 99 Sections Requirements

NEW DIRECTIVES BEING MADE INTO LAW ALL THE TIME

Mike Bullivant

Mike Bullivant

1

MORE TESTING

Mike Bullivant

1

MORE TESTING

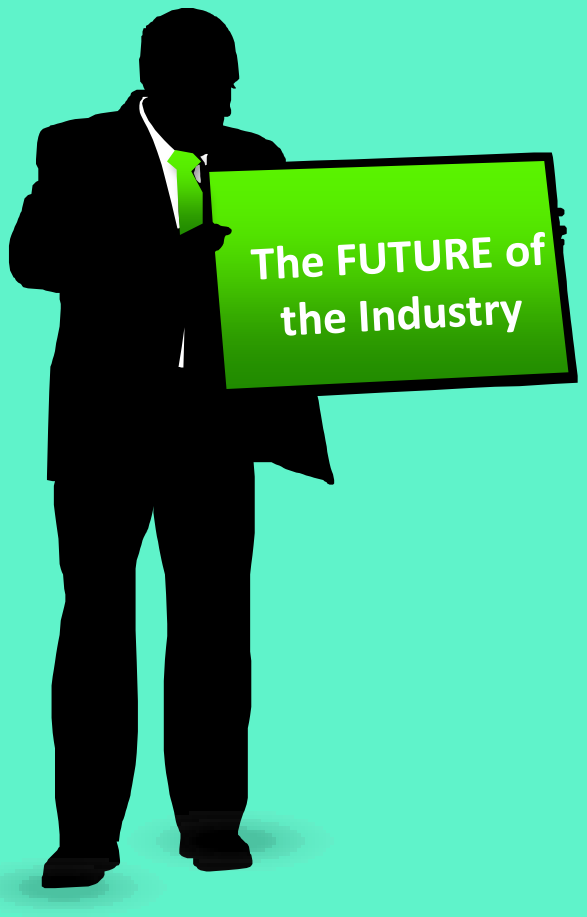
2

HIGHER DEVELOPMENT COST

Mike Bullivant

1. MORE TESTING
2. HIGHER DEVELOPMENT COST
3. LONGER TIME TO MARKET

1. MORE TESTING
2. HIGHER DEVELOPMENT COST
3. LONGER TIME TO MARKET
4. LONGER R.O.I.

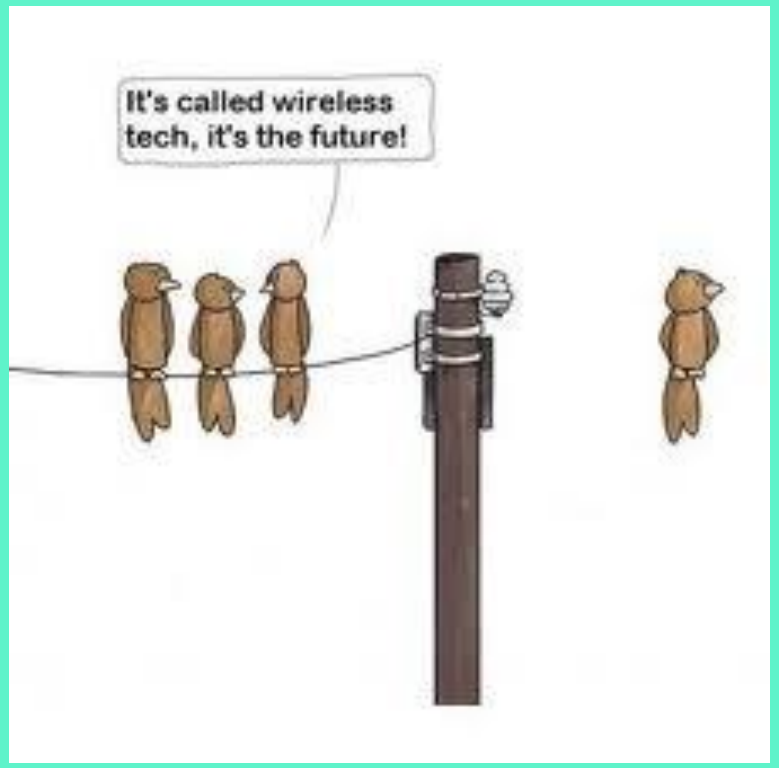

The FUTURE of the Industry

?

If Only !

Progressive Development

Use state of the Art Technology



Resulting in some strange devices

Or some **very** strange devices

Even some scary devices

Be sure of one thing


Future is in
OUR
hands.

THANK YOU FOR LISTENING

Thanks for coming!

Lets Keep Sharing!

CIPS HT Group Website:

http://www.cips.org/en-GB/Community/groups/Health-Technology/

CIPS LinkedIn Group

http://www.linkedin.com/groups?gid=4197381&trk=hb_side_g

CIPS HT Twitter Feed

@CIPSHealthTech

Lee.Robinson@lime-associates.com

Lime Associates
Medical Purchasing & Supply Solutions

CIPS
Chartered Institute of Purchasing & Supply