NAMDET ANNUAL CONFERENCE – 2019

14th November 2019, York Racecourse Conference Centre

Paul Sim

Medical Device Knowledge Manager – bsi

Standards Development, (13485, 14971, 15223),UK, European, International

Associate Member – Association of Anaesthetists, Member of Safety Committee

ABHI Technical Policy Group & Chair of ISOTC 210 Mirror Committee

Barema Council Member

Faculty Member – Healthcare Skills International

Medical Device Regulatory Compliance Consultancy

HCS

Conference theme is:

Training

Risk &

Governance,

Sharing what we know

TRAINING

MDR/IVDR GSPR Annex 1 – Annex 1 Cl 4 (c) Risk Control Measures 5 b Employee Training

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MDR

GSPD

GDPR

Product Liability

Manufactures responsibility for ensuring all staff are appropriately trained and **COMPETENT**

Duty of care

Regulations

Employer

vicarious liability

TRAINING

Product Standards

National Standards – Hospital Clinical staff

Training & Professional Role – Gold Standard – CPD's

Professional Qualifications & Basic Clinical Training for healthcare professionals

Professional Codes of Practise

TRAINING

- **GENERAL SAFETY & PERFORMANCE REQUIREMENTS (GSPR's)**

Annex 1 Chapter 1 Clause 4 (c) – Risk Control Measures

- 4. Risk control measures adopted by manufacturers for the design and manufacture of the devices shall conform to safety principles, taking account of the generally acknowledged state of the art. To reduce risks, Manufacturers shall manage risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable. In selecting the most appropriate solutions, manufacturers shall, in the following order of priority:
- (a) eliminate or reduce risks as far as possible through safe design and manufacture;
- (b) where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated; and
- (c) provide information for safety (warnings/precautions/contra-indications) and, where appropriate, training to users.
- Manufacturers shall inform users of any residual risks.

TRAINING

- **GENERAL SAFETY & PERFORMANCE REQUIREMENTS**

Annex 1 Chapter 1 Clause 5b

- 5. In eliminating or reducing risks related to use error, the manufacturer shall:
- (a) reduce as far as possible the risks related to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and
- (b) give consideration to the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users).

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RISK

RISK

- From ISO 14971:20xx
- Definitions
  - **3.18 Risk:** *combination of the probability of occurrence of harm (3.3) and the severity (3.27) and of that harm (3.3)*
  - **3.3 Harm:** *injury or damage to the health of people, or damage to property or the environment*
  - **3.4 Hazard:** *potential source of harm*
  - **3.27 Severity***: measure of the possible consequence of a hazard*

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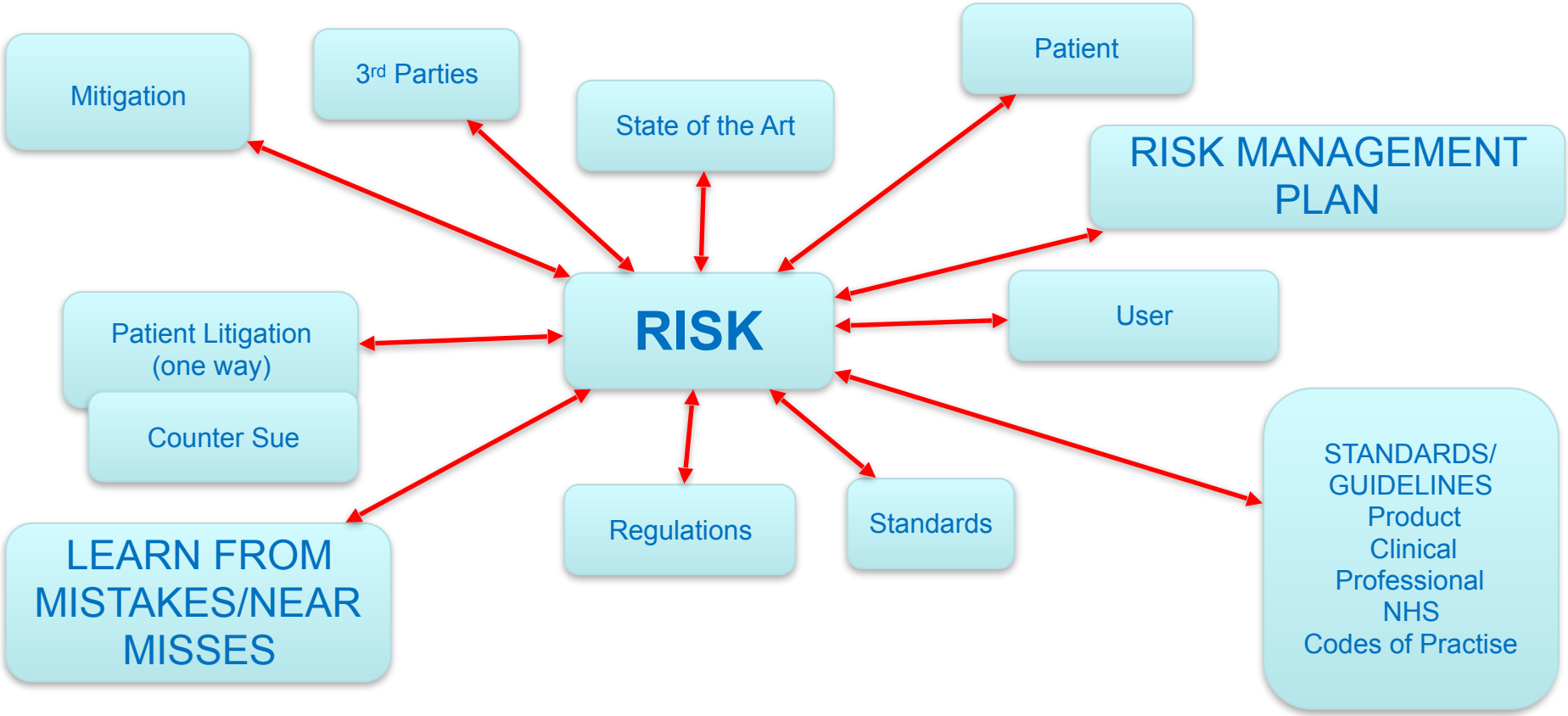
Mitigation
3rd Parties
State of the Art
Patient
RISK MANAGEMENT PLAN
Patient Litigation (one way)
Counter Sue
RISK
User
LEARN FROM MISTAKES/NEAR MISSES
Regulations
Standards
STANDARDS/ GUIDELINES
Product
Clinical
Professional
NHS
Codes of Practise

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In managing Risk and Learning, we often hear the comparison with healthcare and the aviation world.

- Can we learn? Do we?

RISK

- Aviation – Boeing 737 Max 8

- Healthcare – Oxford Incident 2005/Martin Bromley

- Aviation & Healthcare have Regulators, Regulations & Standards – Key to Regulatory Compliance

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RISK

- Aviation
  - **A**ir **A**ccident **I**nvestigation **B**ranch
  - No blame culture
  - Checklists
  - Team working
  - Incredibly safe method of transport
- Healthcare
  - **H**ealthcare **S**afety **I**nvestigation **B**ranch
  - Different culture
  - Checklists in some Clinical disciplines adopted
  - Attempt to remove hierarchical behaviour

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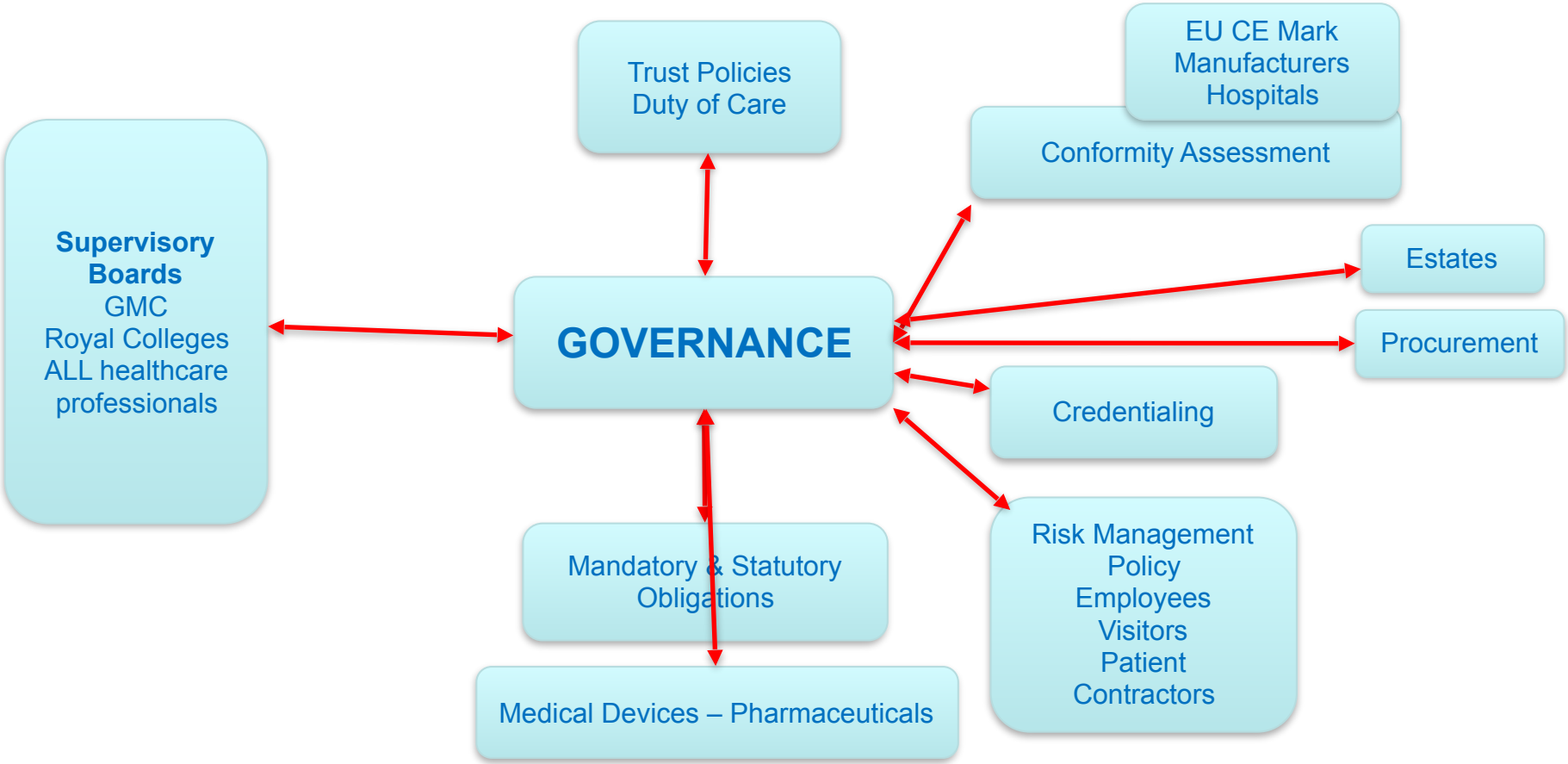
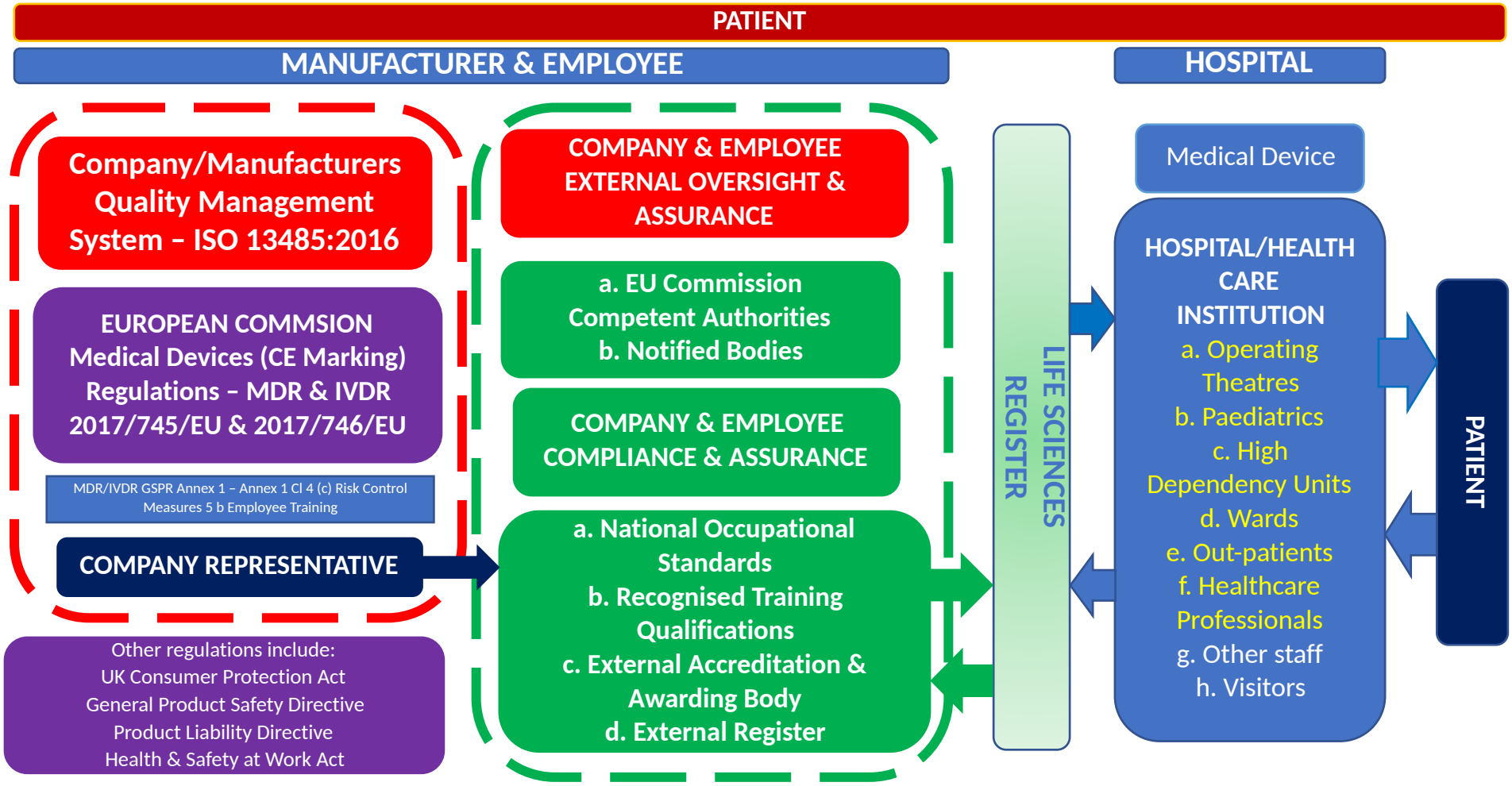
GOVERNANCE

GOVERNANCE

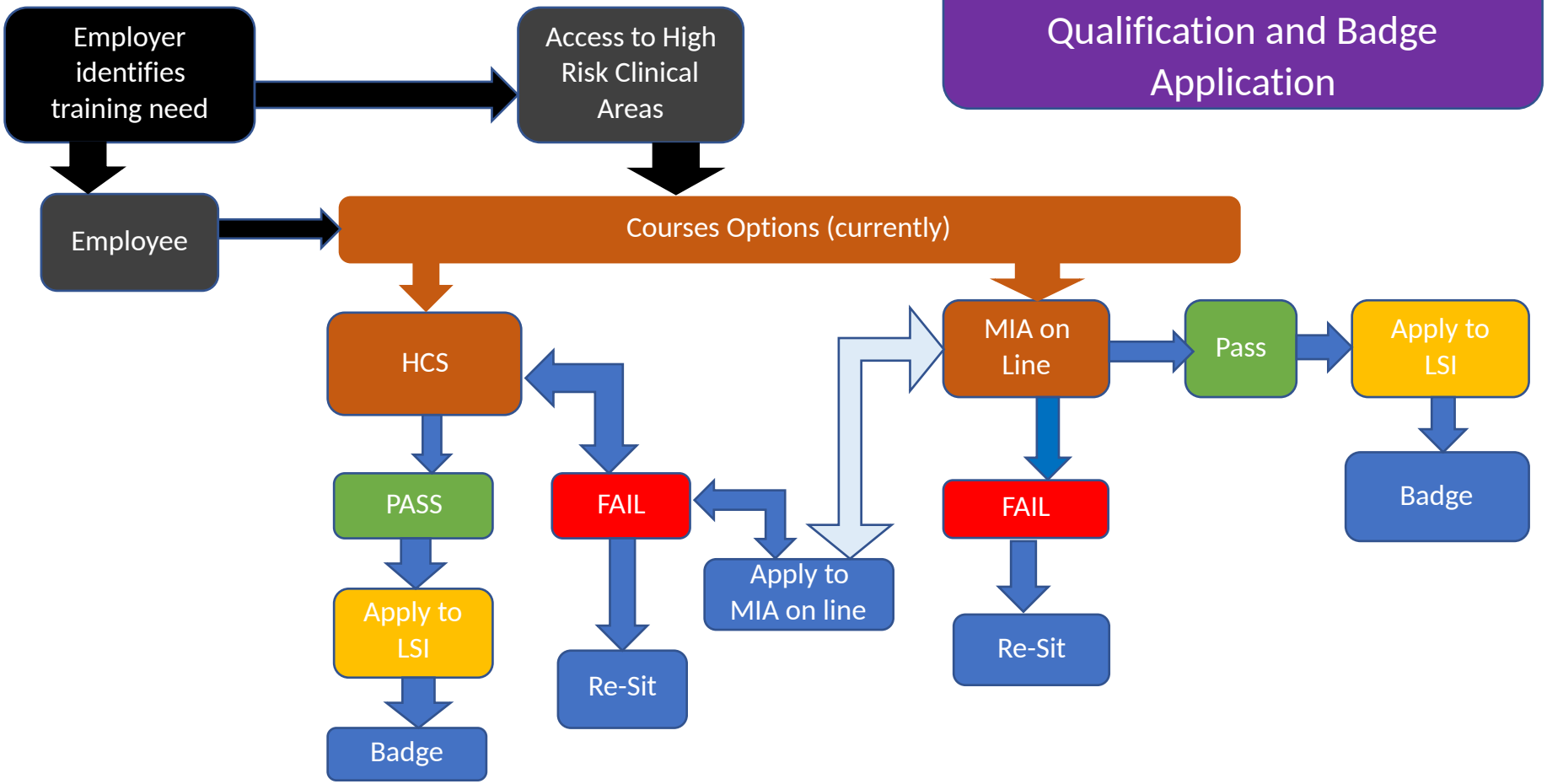

Trust Policies
Duty of Care
EU CE Mark
Manufacturers
Hospitals
Conformity Assessment
Supervisory Boards
GMC
Royal Colleges
ALL healthcare professionals
GOVERNANCE
Estates
Procurement
Credentialing
Risk Management
Policy
Employees
Visitors
Patient
Contractors
Mandatory & Statutory Obligations
Medical Devices – Pharmaceuticals

Life Sciences Credentialing flowchart – Liabilities & Responsibilities



Alternate Routes to qualify for a LSI badge

Credentialing – LSI, PSA, AHSN Qualification and Badge Application



Paul Sim – SiMDC Ltd
26th Sept 2019 Rev0

Questions

Summary

In summary, I have three questions for you?

Do you have a certified (eg ISO 13485) quality management system? and a comprehensive Risk Management Process

Are you fully aware of your obligations under the EU MDR?

What GAPS do you have in your locations, and do you have a plan to remediate, if not you must develop and correct.

- **Conference theme**
- Training
- Risk &
- Governance,
- Sharing what we know

Thank You

Any questions?

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