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MANAGING RISKS IN THE CDU

By: Joy Markey

LET'S TALK ABOUT RISK

"....and right after scissors comes first aid kit."

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PLAYING OUR PART

- The Product/ Device Manufacturer/Supplier are responsible for the design and construction of the devices/Products they have placed on the market
- Where applicable for the development of Information for Use (IFU)
- The Reprocessing Unit has assessed the risks associated with the products it processes and its own activities

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SETTING THE STANDARD

External Standards

HTM01-01 Parts A to E 2016

ISO 15883 Part 2 Washer disinfectors: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.

BS EN ISO 14971:2012 (Annex Z)

UN 3291 (regarding transportation of bio-hazardous waste)

BS EN 285:2015 Sterilization – Steam sterilizers – Large sterilizers

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RISKS HAVE BEEN REDUCED AS FAR AS POSSIBLE, TAKING INTO ACCOUNT…

Available technology and manufacturing advancement of product

Current practices that are deemed to be acceptable (based on standards and guidance)

All known and foreseeable risks that have been identified

The criteria for acceptability of the resulting residual risks should be based on the following.

- Compliance with relevant harmonised standards and/or where appropriate International/local standards and Guidance documents.
- Compliance with the Essential Requirements of the Directive (93/42/EEC)
- Use of 'State of the Art' Risk Control measures, such as Independent monitoring systems, computerised tracking systems.

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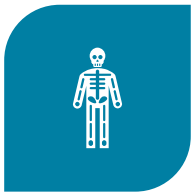
SUPPORTING THE SERVICE



COSHH /JAG/BSI/JCI/SGS RISK ASSESSMENTS

MHRA FIELD SAFETY NOTICES AND MEDICAL DEVICES BULLETINS

INFECTION PREVENTION EXPERT ADVISORY GROUP (IPEAG)

THEATRE/ REPROCESSING UNIT EXPERT ADVISORY GROUPS

DATIX COMPLAINTS REPORTING/ RISK MANAGEMENT SYSTEM

LOCAL RISK MANAGEMENT STRATEGY

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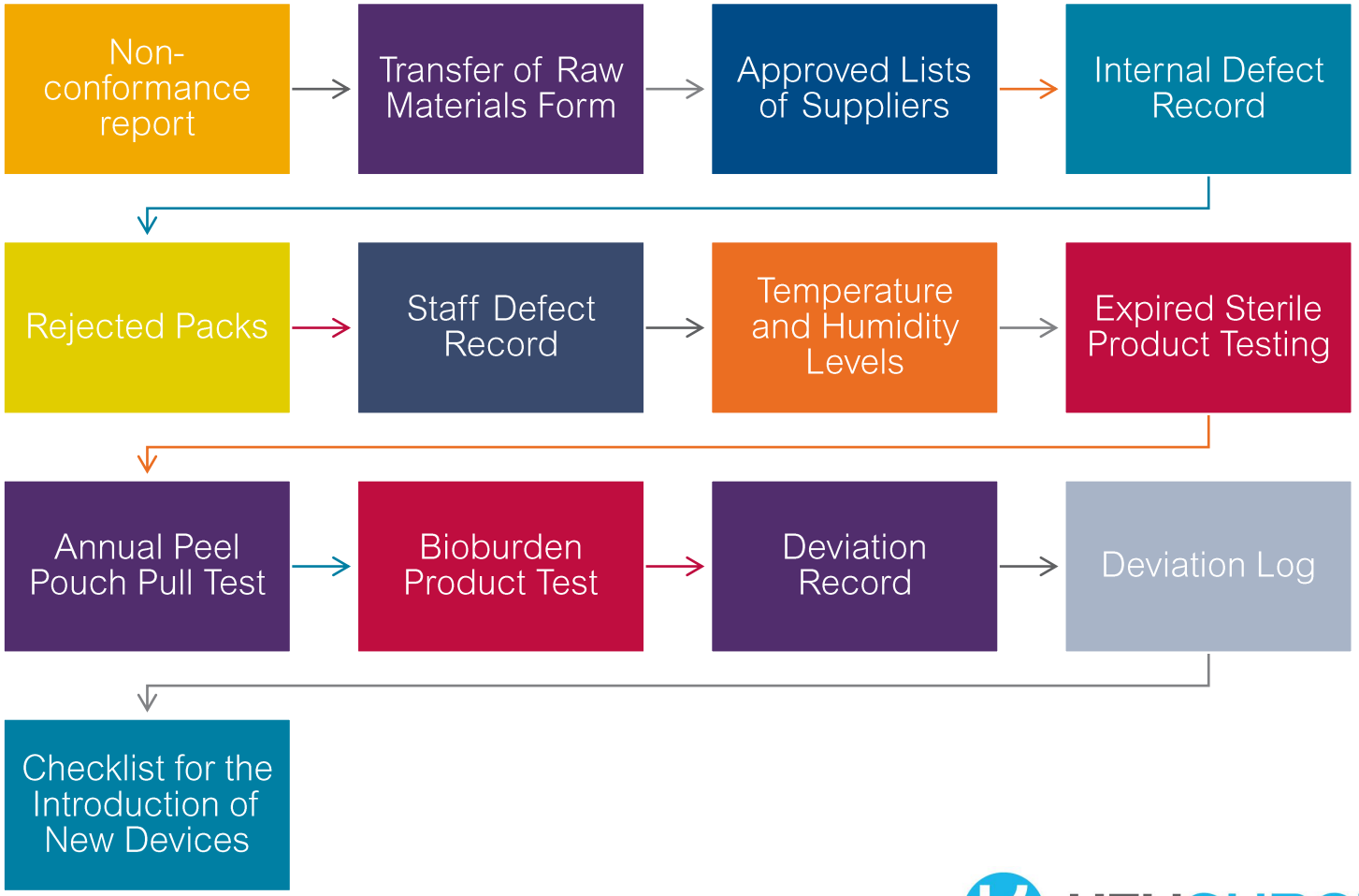
PROCESS AND PRODUCT RISK EVALUATION IN THE CDU



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WHO IS AT RISK?

- Patients
- Staff
- External service providers
- Suppliers

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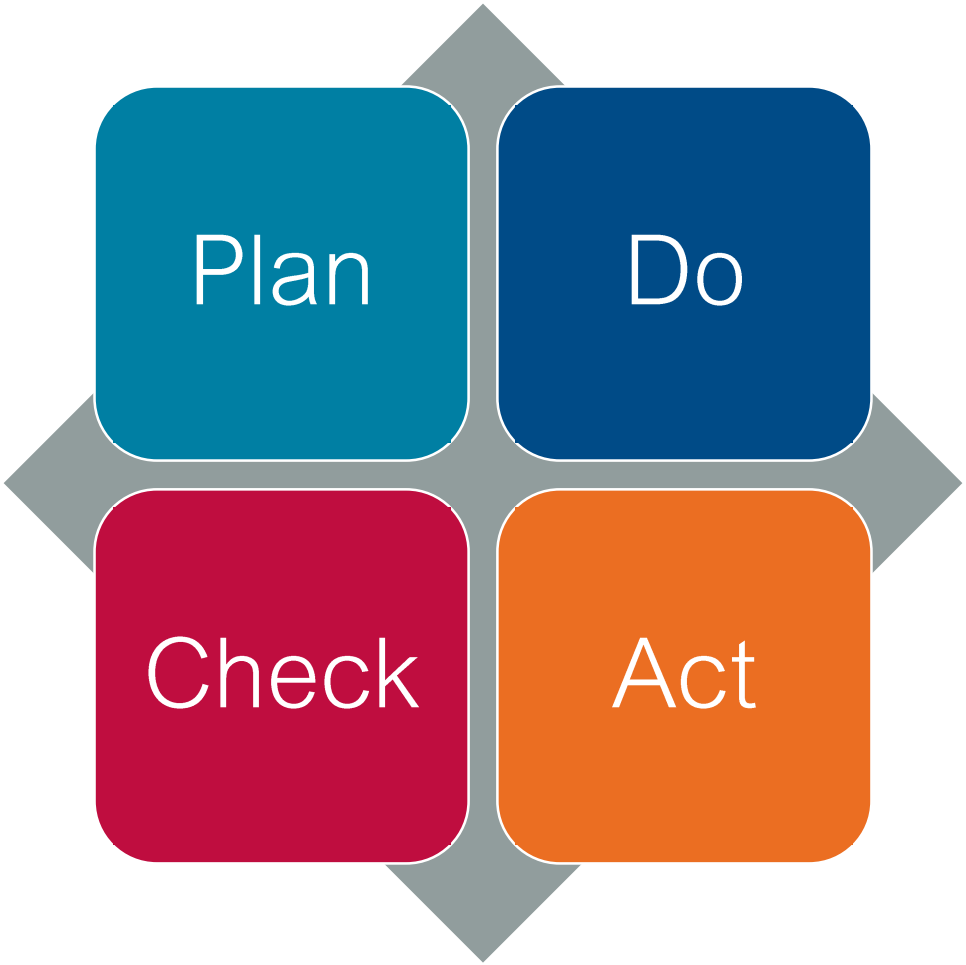
REDUCING THE RISK



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RISK EVAULATION

Actions and controls have been implemented to reduce the risk to a realistic and acceptable level as per Annex Z of BS EN ISO 14971:2012.

Any hazard originally categorised as red (high risk) has had sufficient risk reduction action and controls implemented and documented to ensure that the level of risk is green (low risk).

The consequence (impact or severity) of the hazard cannot be reduced through risk management; however the implementation of actions and controls within the reprocessing Unit and communication with Customers has reduced the likelihood of occurrence, therefore reducing the overall risk.

The Quality Control Team has reviewed the risk analysis and concluded that risks have been reduced as far as possible and that these meet the afore-mentioned acceptance criteria.

Risk reduction has been carried out to an extent which ensures that the Reprocessing Unit products are compatible with a high degree of protection of health and safety.

The resulting risks, when combined, are considered to be acceptable, taking account of the risk–benefit to the patients.

The device Supplier/ manufacturer is responsible for determining the risks associated with bringing their products to market.

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RISK ASSESSMENT GRID (RAG)

1-6	Low risk (considered ‘acceptable’ and cannot be further reduced by any HSSU control or action)
8-15	Moderate risk
16-25	High risk

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Colour Coding as per QSP 05 - Risk Analysis and Management and Group Risk Management Strategy

		Likelihood				
Consequence score		1 Rare	2 Unlikely	3 Possible	4 Likely	5 Almost Certain
5	Catastrophic	5	10	15	20	25
4	Major	4	8	12	16	20
3	Moderate	3	6	9	12	15
2	Minor	2	4	6	8	10
1	Negligible	1	2	3	4	5

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SHARP INSTRUMENTS IN TRAY RAG

2.11.1 Injury to staff or user	Injury to user, loss of work hours, litigation	3	Sharp instruments not protected adequately	Ensure standard packaging methods adhered to and staff are aware of and have access to tip protectors, etc.	4	**12**	Review efficacy and feedback at HSSU meetings with customers. Monitor Defect reports from Customers.	3
2.11.2 Damage to other pack components or consumables	Pack is rendered un-useable or instruments unfit for purpose	3	Sharp instruments not protected adequately	As above	4	**12**	As above and bio-burden testing of sharps protection devices employed in HSSU packs.	3

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KEY SURGICAL SUPPLIER SUPPORT TO CUSTOMERS

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SOLUTION BASED SELLING THE KEY SURGICAL WAY

- Customer focused
- Products fit for purpose
- One stop shop supply chain
- Compliant, safe, reliable
- Tried and tested
- Innovative
- Product application to process need
- Trained sales teams/suppliers
- Consultative selling model

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TRANSFER OF RAW MATERIALS

- Bioburden testing of raw material (if required)
- If converting product at Supplier point ISO 13485
- Transportation certification
- Appropriate packaging systems
- Labelling Systems
- IFU for raw material storage conditions

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REJECTED PACKS

On Site evaluation of reprocessing practices (Audit)

Sterile Store Audit

Product solutions - Support products

User Handling Training

RIGHT PRODUCT FOR PROCESS FOCUS

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EXPIRED PRODUT TESTING

- Sterility testing – Independent (real time)
- Design Idea profiles for stock rotation
- Labelling
- Colour coordinated dated wraps
- IFU

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BIO BURDEN TESTING/EFFICACY OF PROCESS

IFU – Right brush for right device/correct application

Brush user training

Awareness around frequency to change

Instrument efficacy post wash testing

Washer Disinfector efficacy testing (PCD)

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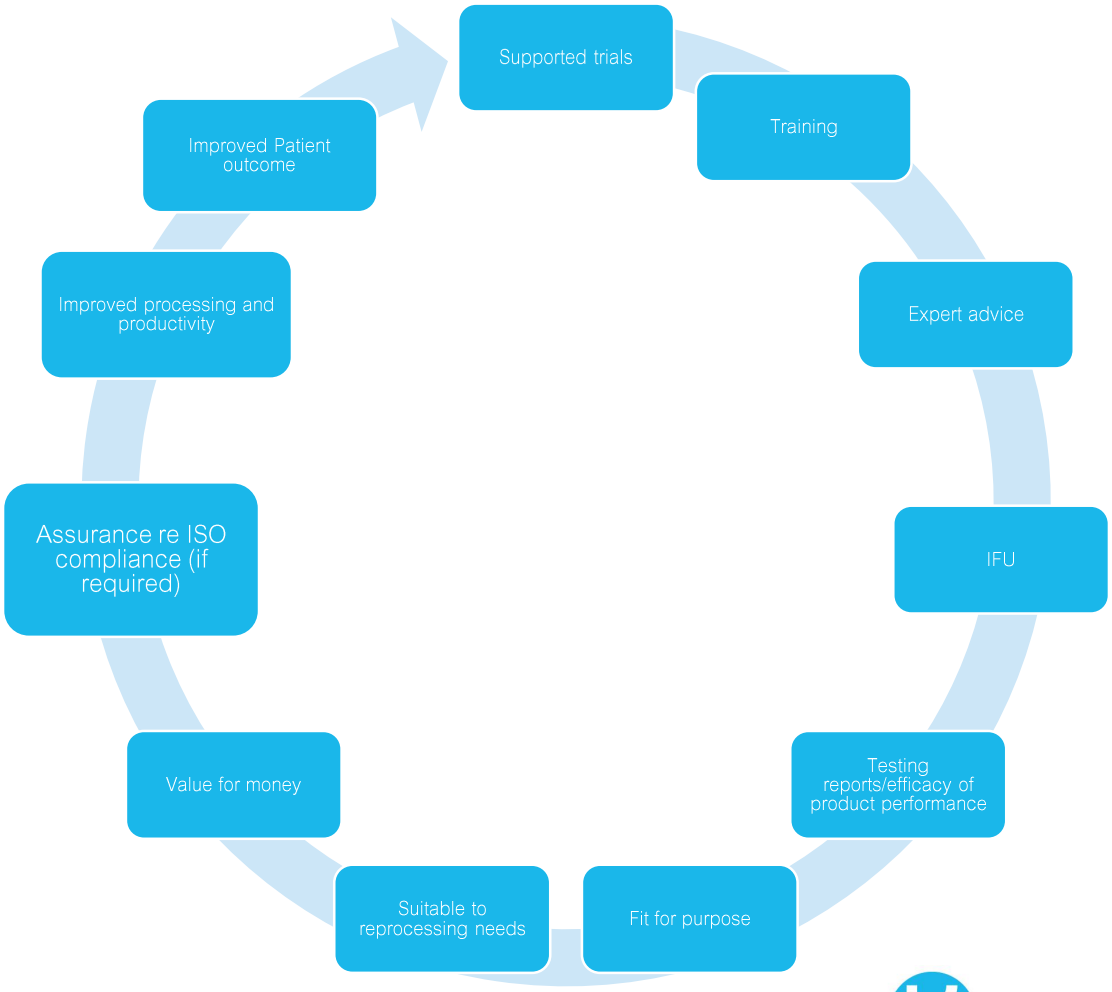
CHECKLIST FOR INTRODUCTION OF NEW DEVICE/PRODUCT



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THE PRODUCT THAT WINS
IS THE ONE THAT BRIDGES
CUSTOMERS TO THE
FUTURE,NOT THE ONE
THAT REQUIRES
A GIANT LEAP.
–AARON LEVIE, CO-FOUNDER OF BOX

THANK YOU!

STAY CONNECTED WITH US:

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