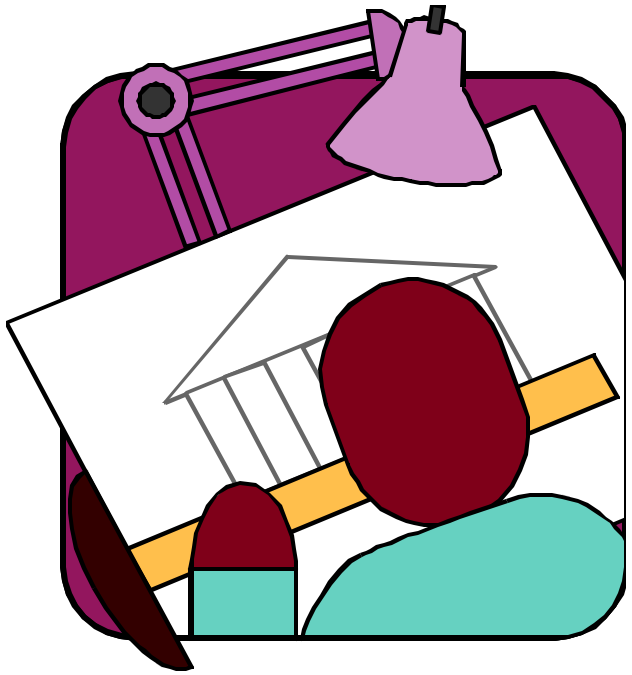
Design Controls and Production & Process Controls

QSIT Workshops

Design Controls



Highlights

Helpful Hints

Personal Experiences

QSIT Progression

1. **Management Controls**
2. ***Design Controls***
3. **Corrective and Preventive Actions**
4. **Production and Process Controls**
5. **Management Controls**

“Top Down”

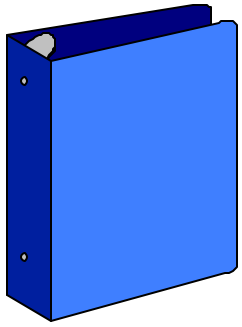


Table 1

Binomial Staged Sampling Plans

Binomial Confidence Levels

Confidence Limit .95≤		0 out of:	1 out of:	2 out of:
A	.30 ucl*	11	17	22
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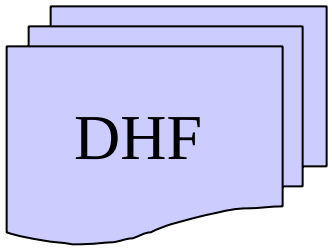
E	.10 ucl	35	52	72
F	.05 ucl	72	115	157



Review Design Control Procedures

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Sample Design Control Records

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Review Design Control Records

A “Top Down” Example...

Were Design Verification Procedures Defined? Documented?

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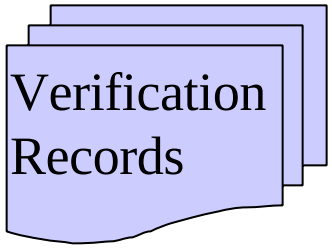
Sample Design Control Records



Do verification activities confirm that design output meets design input requirements? Does the DHF contain the required information?

“Vertical Probes”

- Design Input
- Design Output
- **Design Verification**
- **Design Validation**
- Design Change
- Design Review
- **Design Transfer**

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Focusing the Inspection of Design Controls...

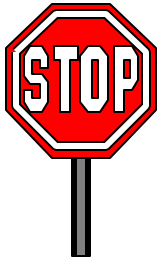
52 Objectives **(Design Control Inspectional Strategy)**

36 Objectives **(Design Control Report and Guidance)**

15 Objectives **(QSIT)**

Design Controls Evaluation...

Safety

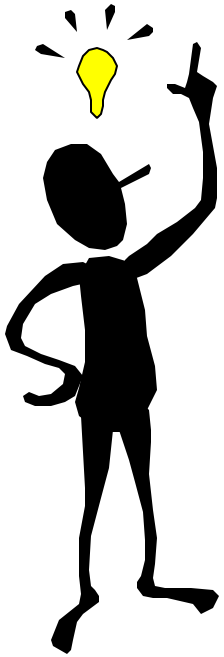


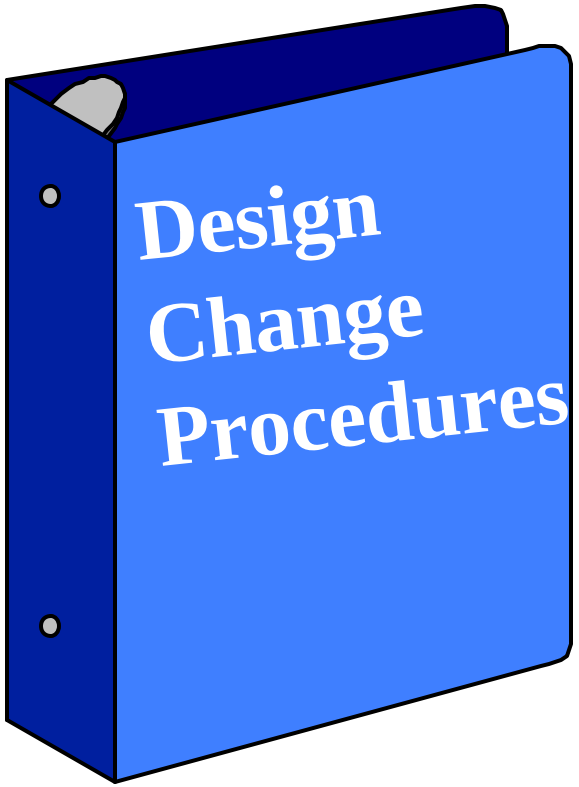
Efficacy

GO! **Process, Methods and Procedures**

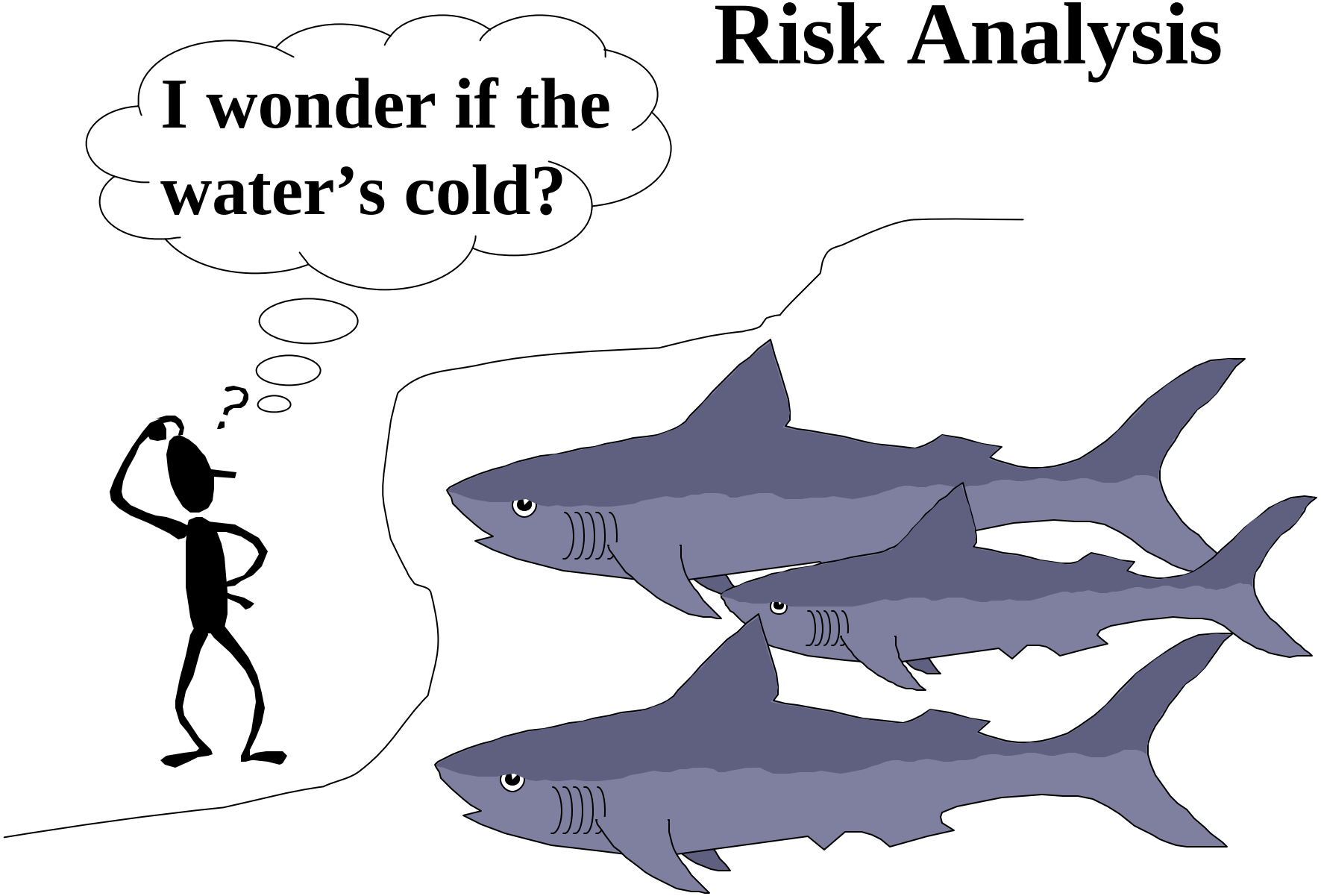
What if I haven't had *any* design activity since June 1, 1997?

Define and Document Design Change Procedures





Risk Analysis



Risk Analysis Quiz! Select the Most Appropriate Statement...

A. Since the requirement for Risk Analysis doesn't appear in the Quality System Regulation until 820.30(g) Design Validation, I may as well wait until then to to start thinking about RA.

B. I better think about RA from the beginning of my design project, including referencing RA in my design and development planning and completing my RA activities prior to completing Design Validation.

C. I wonder if the water's cold?

Design Verification and Design Validation in a Nutshell

Design *Verification*…

Did I make the product right and can I prove it?

Design *Validation*…

Did I make the right product and can I prove it?

Design Validation and Process Validation in a Nutshell

Design Validation…

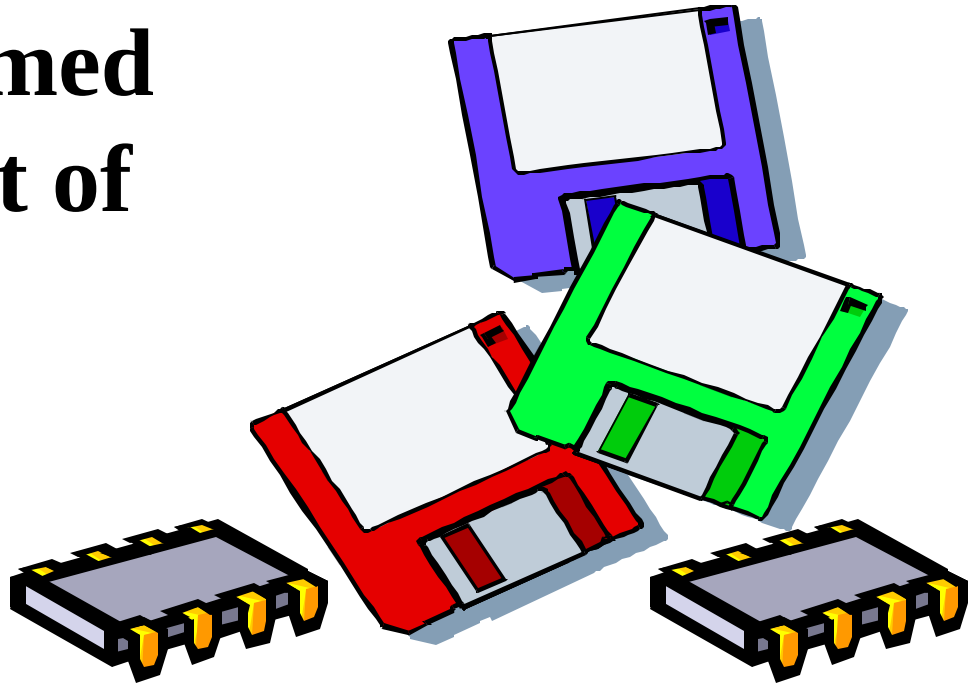
Did I make the right product and can I prove it?

Process Validation…

Does the process consistently produce a result or product meeting predetermined specifications and can I prove it?

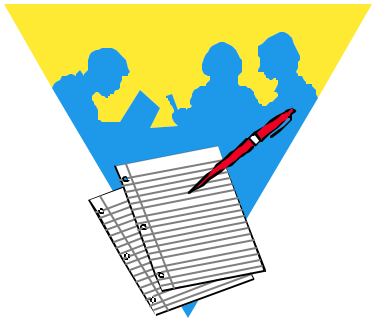
Medical Device Software

Validation confirmed during assessment of Design Controls



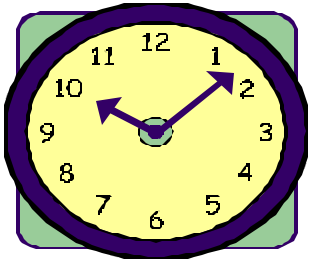
Design Reviews

- Purpose



- Participants

- Timing



QSIT Progression

1. **Management Controls**

2. **Design Controls**

3. ***Corrective and Preventive Actions***

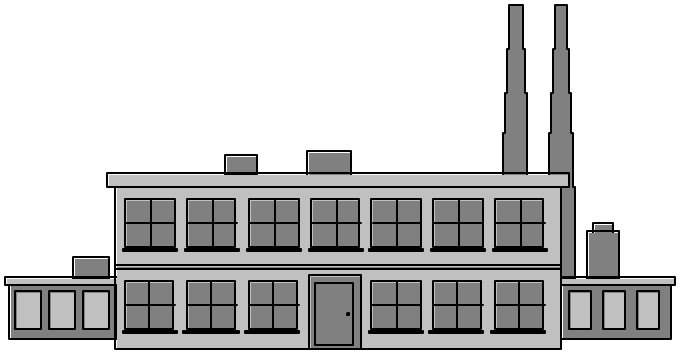
4. **Production and Process Controls**

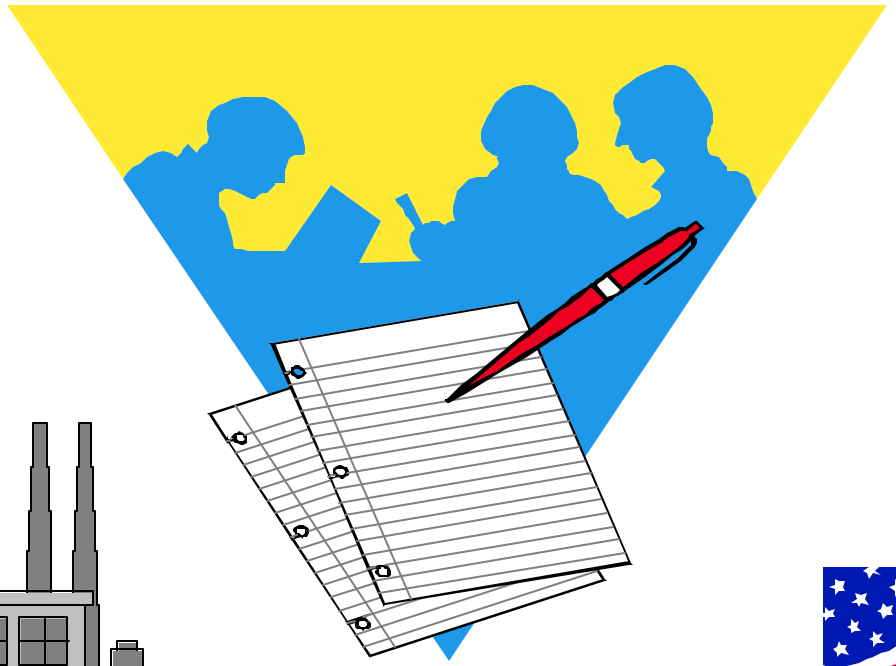
5. **Management Controls**

Design Controls Helpful Hints...

- **Understand the jargon ("…the special or technical vocabulary of a science, art, profession…") Webster's**
- **Use the results of Risk Analysis throughout your quality system (purchasing controls, acceptance activities, failure investigation, etc.)**
- **Be prepared to discuss Y2K**

My Experiences...





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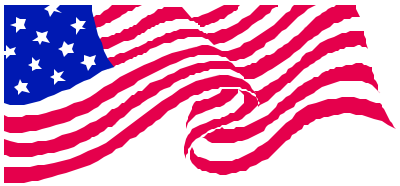

Production and Process Controls (P&PC)

Highlights

Helpful Hints

Personal Experiences

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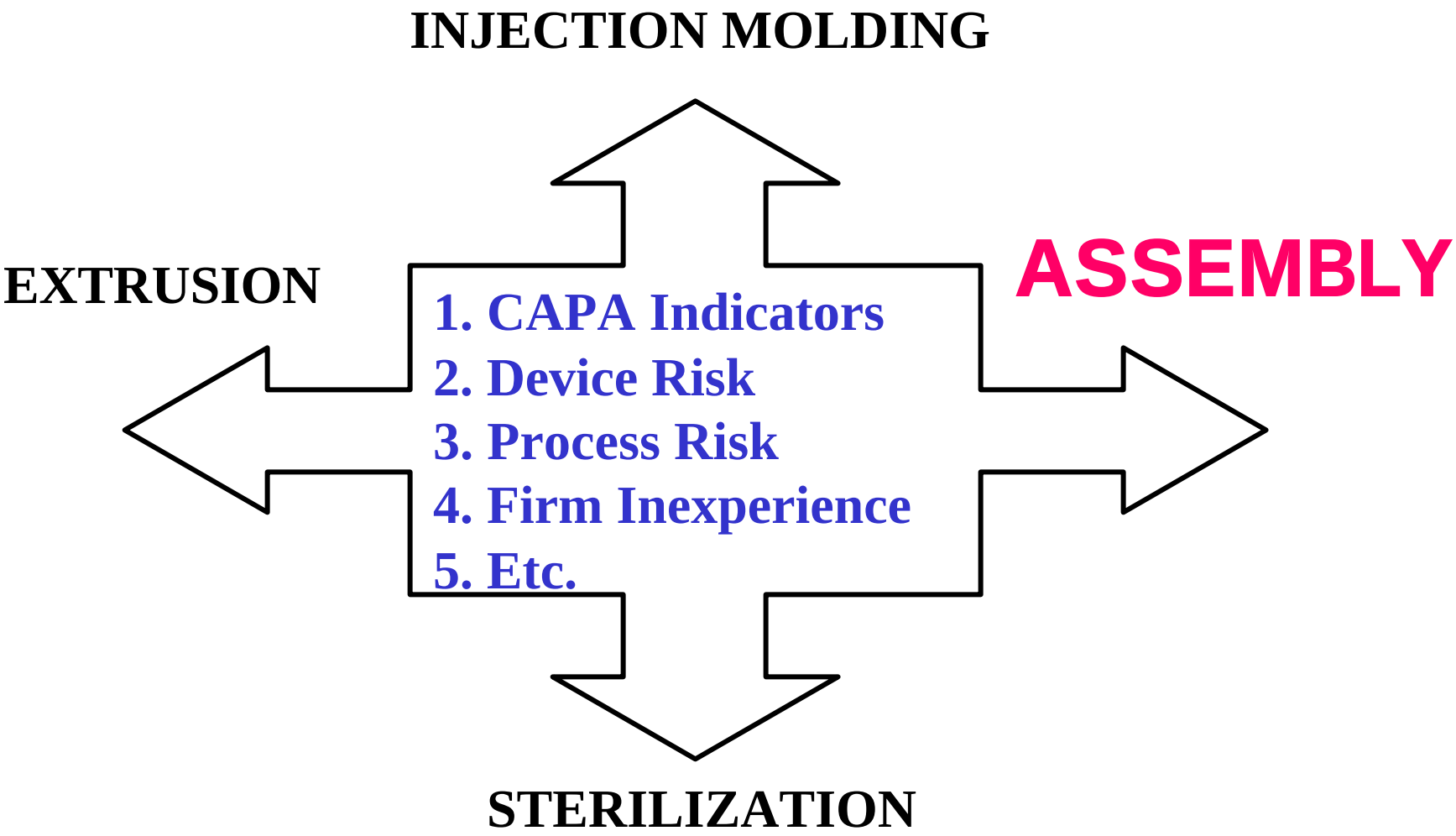
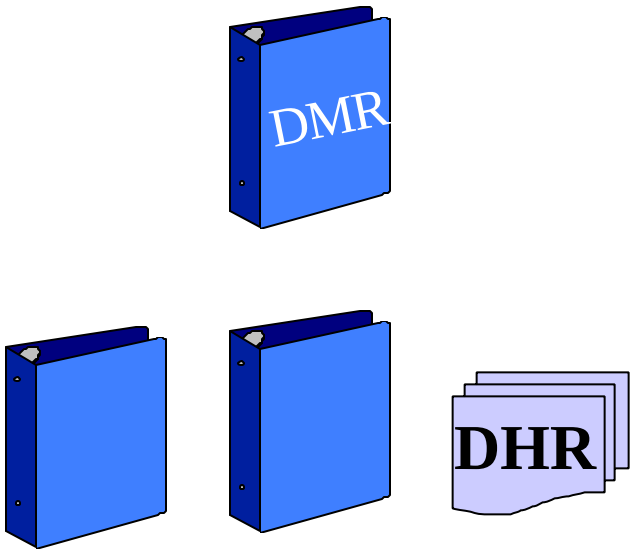
The Inspection of P&PC...





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Review Device Master Record

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Review Shop Floor Procedures and “Real Time” Operation

⇩ ⇩

Sample DHR’s From All Shifts

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Review Historical Process Performance

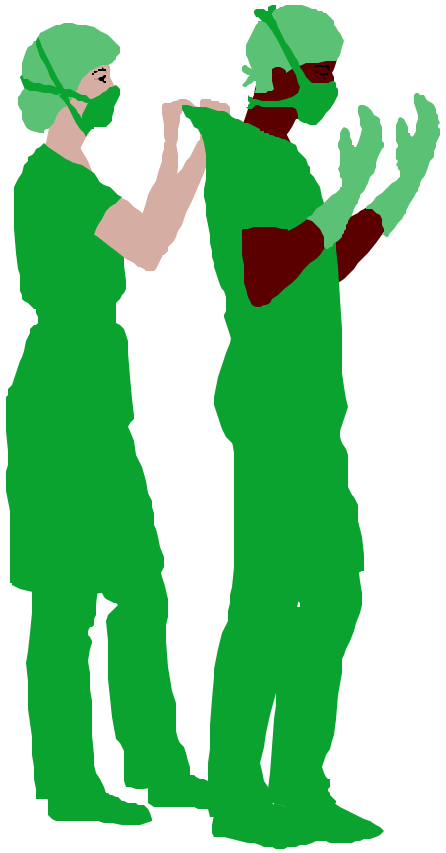
Plus...

- ☑ **Purchasing**
- ☑ **Acceptance**
- ☑ **Buildings & Equip.**
- ☑ **Calibration**
- ☑ **Personnel**
- ☑ **Statistical Tech.’s**
- ☑ **Others**

P&PC “Satellite”

“Sterilization Process Controls”

Includes a technique for inspecting the unique aspects of sterile medical device manufacturing ...



P&PC Quiz! Select the Most Appropriate Statement...

A. **Process Validation and Sterilization will be covered during every QSIT inspection.**

B. **QSIT defines criteria for the selection of a manufacturing process to be inspected and investigators should avoid selecting the same process every time the firm is inspected.**

C. **I wonder if the water's cold?**

Automated Processes

- Requirements
- Validation Protocol
- Validation Activities
- Validation Results
- Change Controls

Is the Process Operating Within Specified Limits?

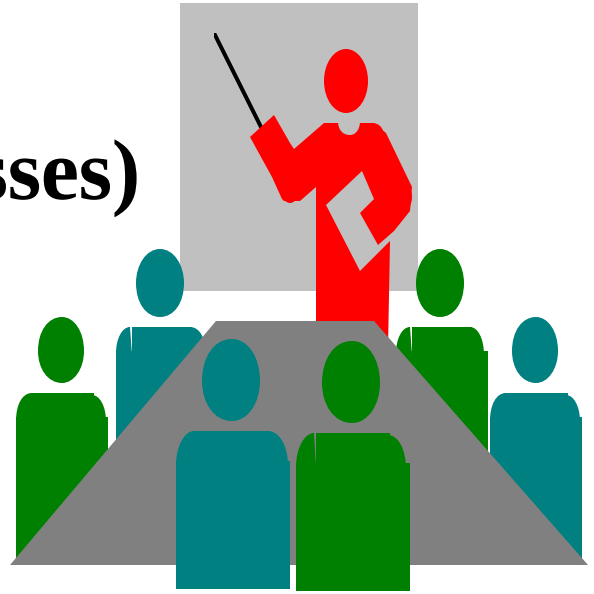
If NO, then review…

- **Nonconforming Product Controls**
- **Resulting CAPA's**
- **Equipment Adj., Cal. & Maint.**
- **Validation (where required)**

Personnel Training and Qualification

Confirm all shifts are...

- **Trained**
- **Qualified (Validated Processes)**
- **Aware of Defects & Errors**



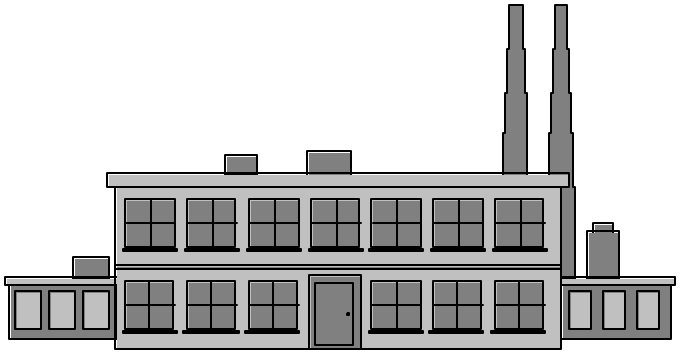
QSIT Progression

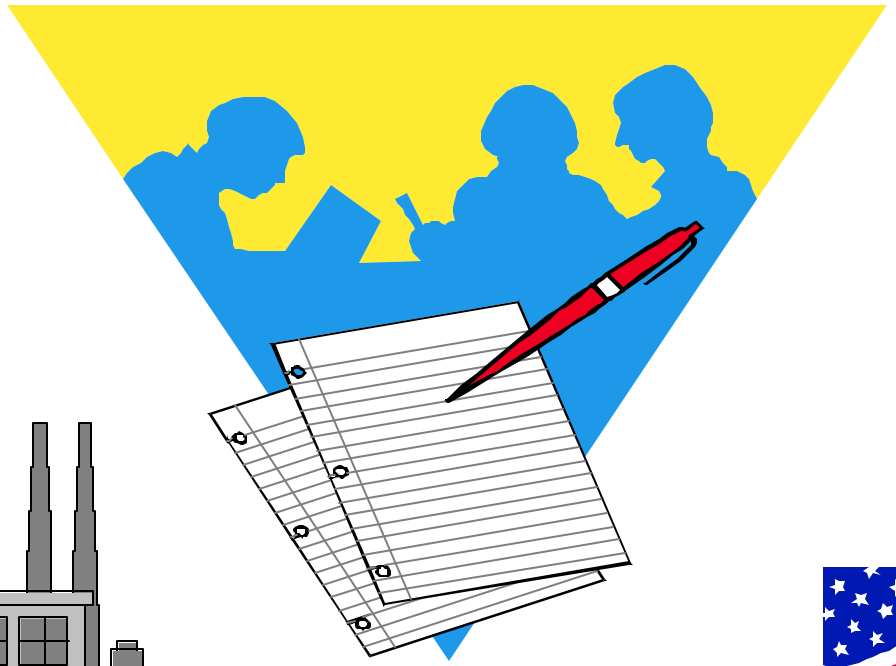
- ☑ 1. Management Controls
- ☑ 2. Design Controls
- ☑ 3. Corrective and Preventive Actions
- ☑ 4. Production and Process Controls
- *5. Management Controls*

P&PC Helpful Hints...

- **A "Master List" of documents helps the inspection move along efficiently**
- **Understand the "linkages" (e.g. Purchasing Controls, Acceptance Activities, Nonconforming Product Control, CAPA, Personnel, etc.)**

My Experiences...





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