

# Standardisation & SOPs, Training & Competency

*Lesley Bust, South Africa*

— IPFA 2<sup>nd</sup> ASIA WORKSHOP —  
PLASMA QUALITY  
*and* SUPPLY  
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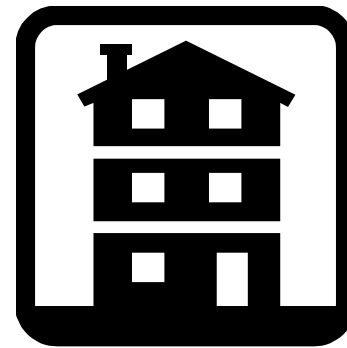
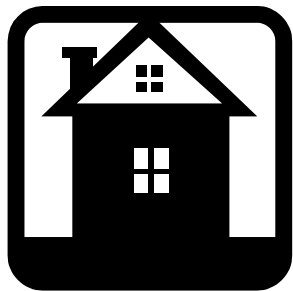
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# Quality Management Systems

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- Many different shapes and sizes
- Each organisation to build a system that suits it's needs
- Use legislation and literature
- Adapt, tweak and model to build own system
- implement and follow
- *Document what you do, do what you document!*



# Nobody likes paperwork so why bother?

No SOPs

No policies

No records

No specifications



# Standardisation

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- Without SOPs and other documents staff would:
  - *Rely on other staff*
  - *Do job from memory*
  - *Get creative and take shortcuts*
  - *Do things their own way*
- SOPs ensure standardisation
- Procedures done in same way consistently by everyone



# Writing SOPs

- Need SOP for each activity impacting quality
- Find document champions
- Train on how to write SOPs
- Create breakdown of key steps
- Use process flowcharts to map processes
- Perform usability test
- Train staff on SOP before implementing



# Ten Top Tips

1. Chose a concise heading
2. Keep SOP simple and short
3. Use clear language and common terms
4. Write in instruction format
5. Break flow of text:
  - *Use blocks or tables*
  - *Include diagrams*
  - *Add flowcharts*



# Ten Top Tips (cont'd)


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6. Keep numbering simple
7. Use bullets and hyphens
8. Limit signatures
9. Make documents attractive
10. Protect them from damage

*Create a sense of document pride!*



# Example

DOCUMENT NUMBER: CTN-S02	PAGE NO: 1 of 1	 <i>BTS</i>
TITLE: <b>MAKING TEA FOR MANAGER</b>	EFFECTIVE DATE: 03/04/2017	
APPROVED BY:	AUTHORISED BY:	

## PREPARATION

1. Check that manager is in office at tea time.
2. Place tea cup on tray and add one tea bag.
3. Fill milk jug and place on tray.

## MAKING & SERVING TEA

1. Fill kettle with tap water.
2. Plug kettle in and switch on.
3. Switch off kettle when water is boiling.
4. Pour water in cup on tray allowing space for milk.
5. Allow tea bag to steep for 3 minutes then remove and discard in bin.
6. Carry tray to manager's office and place on desk.



# TRAINING

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# Requirements for Staff

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- Most important resource in any organisation
- Requirements for personnel:
  - *Sufficient numbers*
  - *Appropriately qualified*
  - *Experienced*
  - *Trained*
  - *Competent*



# Training Stages

- Induction training:
  - *Tour of premises*
  - *Introduction to key staff*
  - *HR policies, values and ethics*
  - *Safety and health requirements*
  - *Introduction to quality systems*
- Initial on-the-job technical training
- Continuous training, externally or in-house



# On-the-job Training

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- Includes theory and practical training per Job Description and SOPs
- Generally done by supervisor or experienced staff
- General procedure for trainee:
  - *Read SOPs*
  - *Watch demonstration of procedure*
  - *Perform procedure under observation*
  - *Perform procedure independently*
  - *Trainer declares trainee competent*



# Continuous Training

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- Changes in procedures, new regulations, techniques, equipment or software
- Refresher training
- Additional courses
- System needed to determine training needs
- Use training matrix



# Training Records

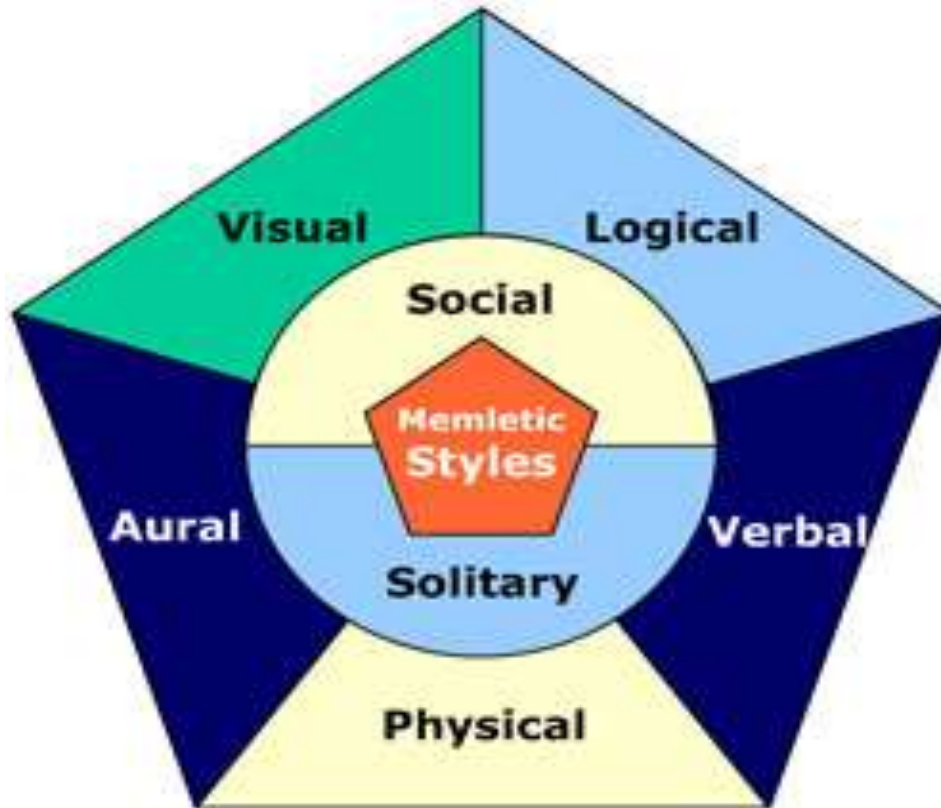
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- If it wasn't recorded, it didn't happen!
- Records should include:
  - *Dept where training took place*
  - *Name & signature of trainee and trainer(s)*
  - *Dates of specific training*
  - *Details of training eg. SOP numbers, tests, methods, equipment etc*
  - *Number of tests done*
  - *Declaration of competence*



# Learning Styles

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# Attributes of Trainers

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- ✓ Trained in how to train
- ✓ Excellent communication skills (verbal, non-verbal and written, good listener)
- ✓ Command respect but non-threatening
- ✓ Be enthusiastic, energetic and creative
- ✓ Flexibility and ability to think fast
- ✓ Good organisational and time management skills
- ✓ Be supportive and encouraging
- ✓ Exhibit patience





# COMPETENCY



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# What determines competency?

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# Competence on SOPs

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- When each new or updated SOP is issued, Supervisor to determine competence of staff on that procedure
- Level of competence may not be same for all staff
- Supervisor to determine action required:
  - *Read only*
  - *Instruction or demonstration*
  - *Observation*
  - *Training*



# Why assess staff competency?

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- Regulatory requirements
- To ensure staff are capable of doing their jobs
- To confirm performance at required standard
- Due to critical nature of work
- Good practice for sustainability
- To monitor changes in performance over time



# Why repeat competency assessment?

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- Competence may not remain constant throughout a person's career
- Competence affected by:
  - *Health issues*
  - *Personal circumstances*
  - *Increased stress levels*
  - *Memory loss*
  - *Change in attitude*



# How is competence assessed?

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- Different ways possible for annual assessment:
  - *Job observation*
  - *Review of work produced*
  - *When signing off work or results*
  - *Review of errors and non-conformances*
  - *Evaluation of safety incidents & accidents*
  - *Review of training done*
  - *Overview of proficiency test results*
  - *Overview of QC on products produced*
  - *Outcome of staff performance appraisal*



# What if not competent?

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- Staff may be found not to be competent *at the time of the assessment*
- Actions to take:
  - *Staff to re-read SOPs*
  - *Re-demonstrate technique to staff*
  - *Retraining*
  - *Counselling*
  - *Monitor performance*
  - *Remedial action*



# All in a nutshell ...



Email: [Lesleybust@outlook.com](mailto:Lesleybust@outlook.com)

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**Thank  
You !**