

Fig 5-1 Prep for Clinical Trial

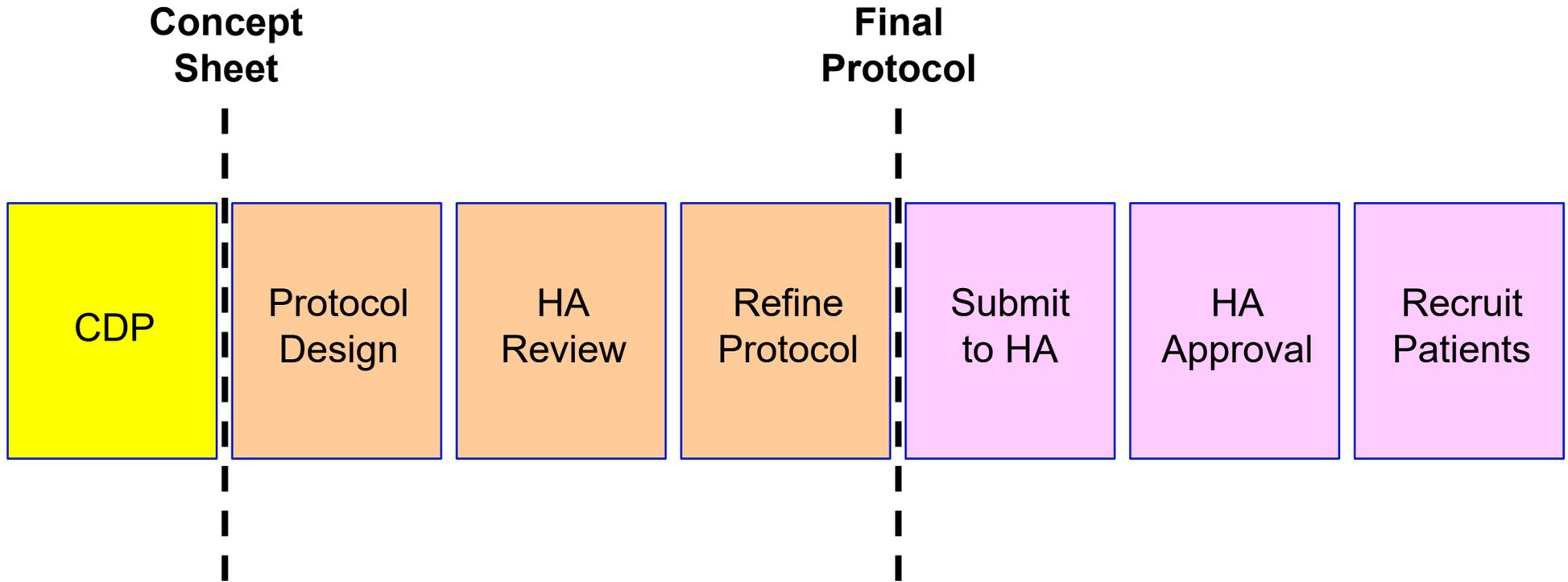


Fig 5-2 Root Cause Analysis Techniques

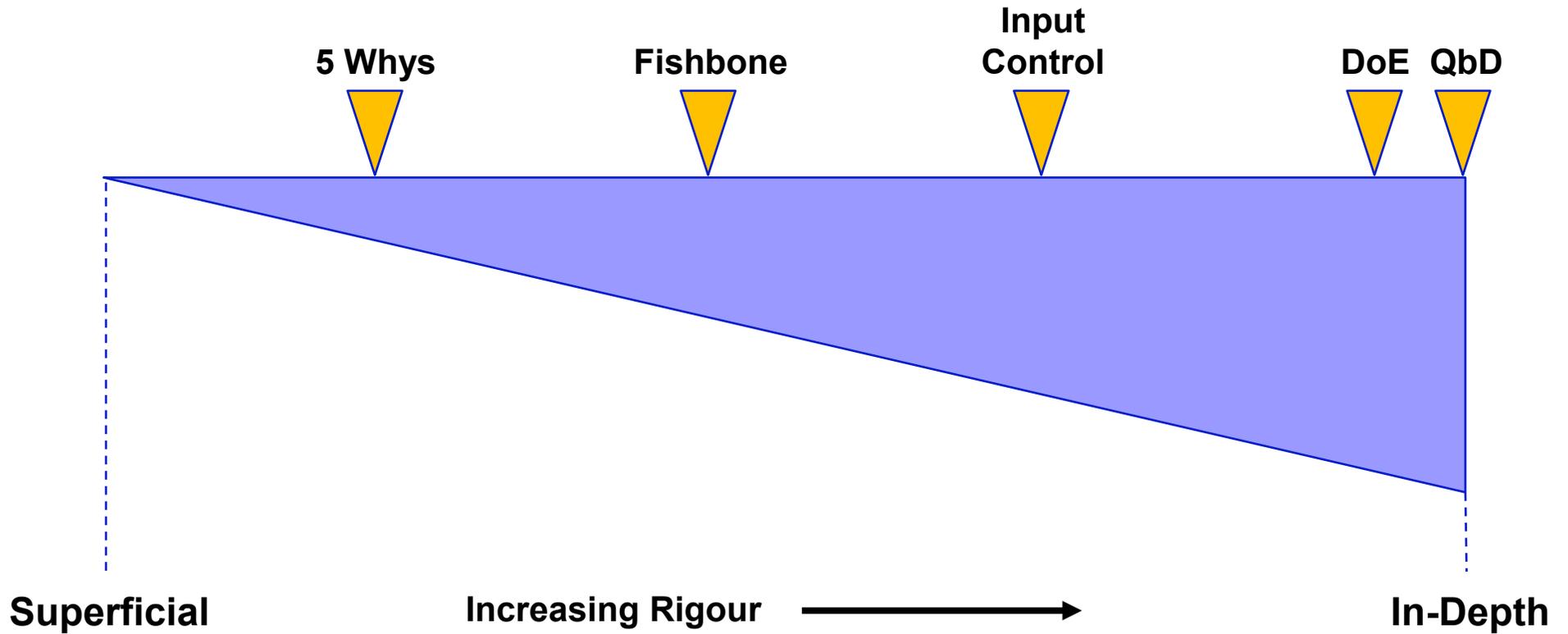


Fig 5-3 Ishikawa Fishbone Diagram

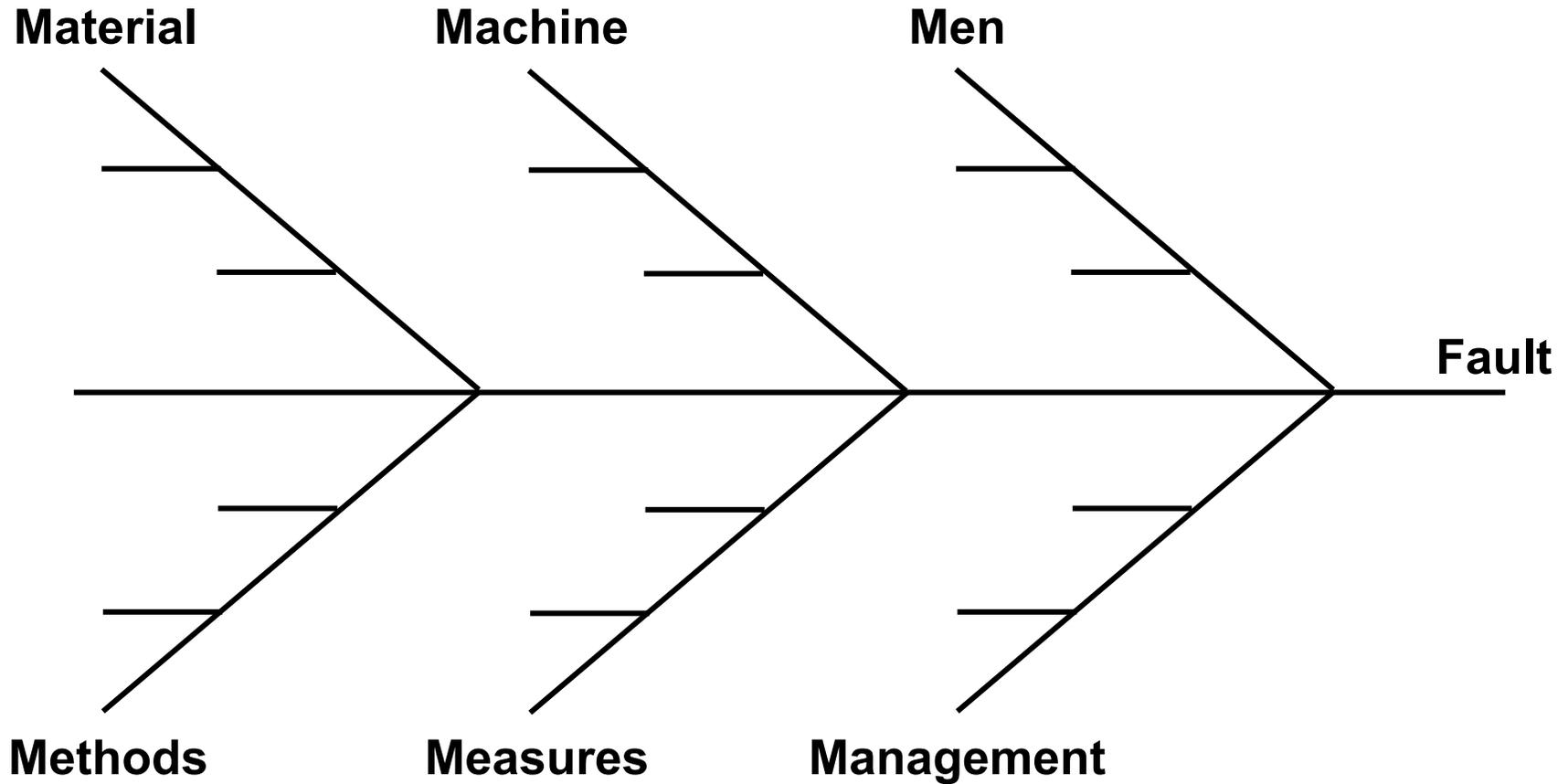


Fig 5-4 Foolproofing

- What do you have to do to get your foolproofing right physically?
- What do you have to do in terms of information on your foolproofing solution?
- How do you ensure compliance by all affected parties?
- Put the solutions in place
- Monitor the results

Fig 5-5 MBR Example (Liquids)

<p>12. Transfer 1800l of purified water to the manufacture tank. Ensure that the temperature of the water is 15 – 25C. Ensure tank mixer is on at 55 – 80 rpm</p>	<p>Tank ID CMS Mixer ID Tank Mixer ID 2300004 K134 Purified Water Volume Check..... Temperature Check Tank Mixer On Tank Mixer Speed</p>	<p>Sign</p>	<p>Sign</p>	<p>Date</p>
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- Too many entries required
- Cramped signature and date spaces
- Prone to errors and omissions – currently only 50% RFT

Fig 5-6 MBR TYM Example (Liquids)

Step	Mat'l ID			Op'r	Check	Date
12A	2300004	Transfer 1800l of K134 purified water to manufacture tank	Tank ID	T431C		
12A	N/A	Volume Check				
12B	N/A	Ensure temperature of water is 15 – 25C	CMS Mixer ID	M194		
12B	N/A	Temperature Check				
12C	N/A	Ensure tank mixer is on at 55 – 80 rpm	Tank Mixer ID	M197		
12C	N/A	Tank Mixer Speed Check				

- Entries reduced from 28 to 12 (57%)
- Colour coded entries – blue for value – cannot move on till green complete
- Simpler, easier to follow, less chance of errors – aim for 100% RFT

Fig 5-7 Milestone 5. Right First Time – Briefing Document

SCOPE: To complete all ACD batch records right first time.
To eliminate all deviations but resolve within 24h any that occur

KEY CHANGE ISSUES:

- Simplify and improve batch records
- Have QA available in production
- Review all deviations in last twelve months
- Develop improvement program to eliminate deviations

CRITERIA FOR SUCCESS:

- When batch records from production are 100% RFT
- When we have no deviations for three months

Fig 5-8 Milestone 5. RFT – Activity Plan

