

品管產品的種類

- Manufacturer Controls (依附測試試劑品管液)
- Third Party Controls (獨立或第三方品管液)
- In-house Control (實驗室自行配製)



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品管產品的基質

- Aqua (水)
- Animal Matrix (動物基質)
- Human Matrix (人類基質)



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品管產品的濃度

- Normal (正常值)
- Cutoff (臨界值)
- Abnormal/Pathological High/Low (異常高/低值)



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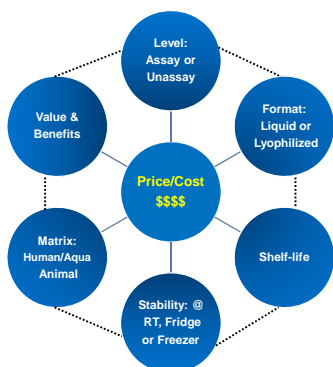
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選擇品管產品時需要考慮的因素

1. Shelf life (產品的有效期限)
2. Liquid format (液態且無須配製)
3. Lot allocation (是否可提供相同批號)
4. Number of analytes (可供分析項目的數量)
5. Analyte concentration (分析項目的濃度)
6. Open vial stability (產品開封後使用期限)
7. Quality assurance program (是否提供實驗室間比對計劃)
8. Price (產品價格)

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性價比 (C/P Ratio)

何謂性價比: “性能 (Capability)” 相對於“價格 (Price)” 的比值

• 包括:

1. Shelf life (產品的有效期限)
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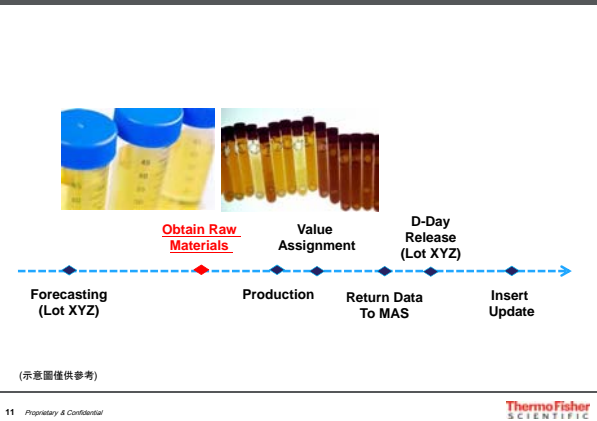
從原料到成品



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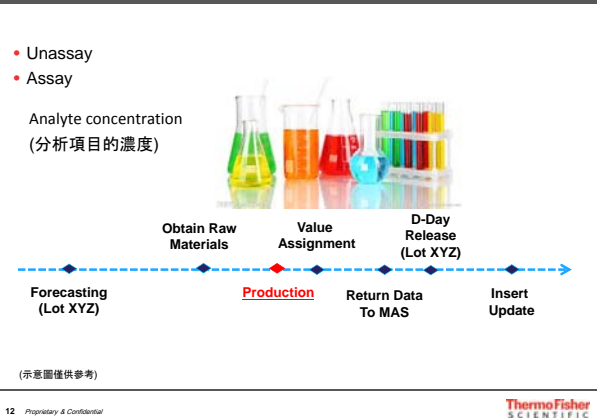
品管產品的製造



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品管啟始範圍的建立

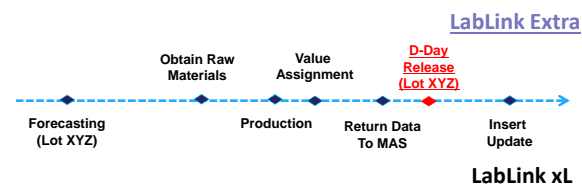


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品管啟始範圍的建立

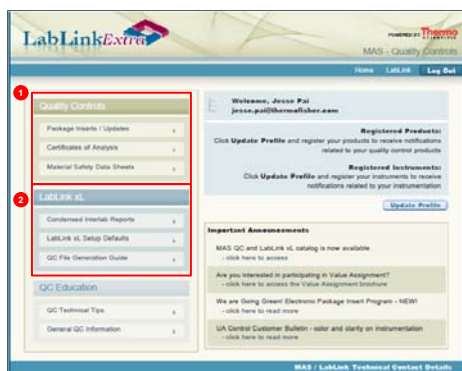
- Unassay
- Assay
 - How to set the insert range (2 SD or 3 SD?)
 - Value Assignment Protocol (如何賦值)
 - Determine Range



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LabLink Extra – www.maslablink.com

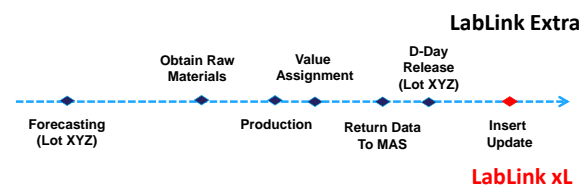


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品管啟始範圍的建立

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LabLink xL 實驗室間品管數值比對計劃

- A website: www.maslablink.com
- A quality assurance program (QAP) or interlaboratory program
 - **Definition:** A means by which laboratories are able to submit QC data and receive comparative reports on inter-laboratory QC program



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品管數值 vs 檢體結果

當試劑批號更換時 品管對試劑批號更換時產生的差異, 如何釐清?

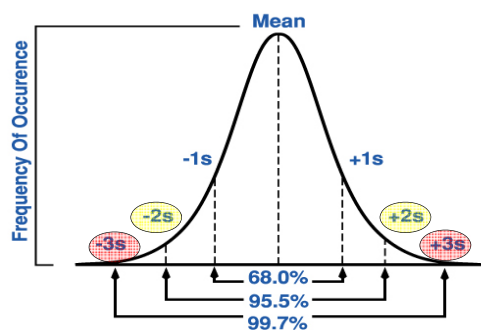
1. 精密度是否會改變?
2. 品管結果是否會改變? (有改變: 如何應對?)
3. 病人結果是否會改變?



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Normal Distribution



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結語

- 如何選擇合適的品管產品
- 建立實驗室的品管系統
- 明瞭並正確使用 Westgard Rule(s)
 - Single Rule (2S) or Multi Rules
 - Warning Rule or Rejection Rules
 - Repeat QC or Re-Calibrate
- 避免誤用"參考用數值" - 建立自己的品管數值範圍*

* Resource: www.westgard.com; C24-A3, CLSI (TSLM)

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