

**ThermoFisher**  
S C I E N T I F I C

## **Our Commitment to Exceptional Quality** **ISO 18385:2016 & Beyond - HIDS 2016**

*Colin McEnaney – Senior Quality Manager Warrington Manufacturing Facility*

The world leader in serving science

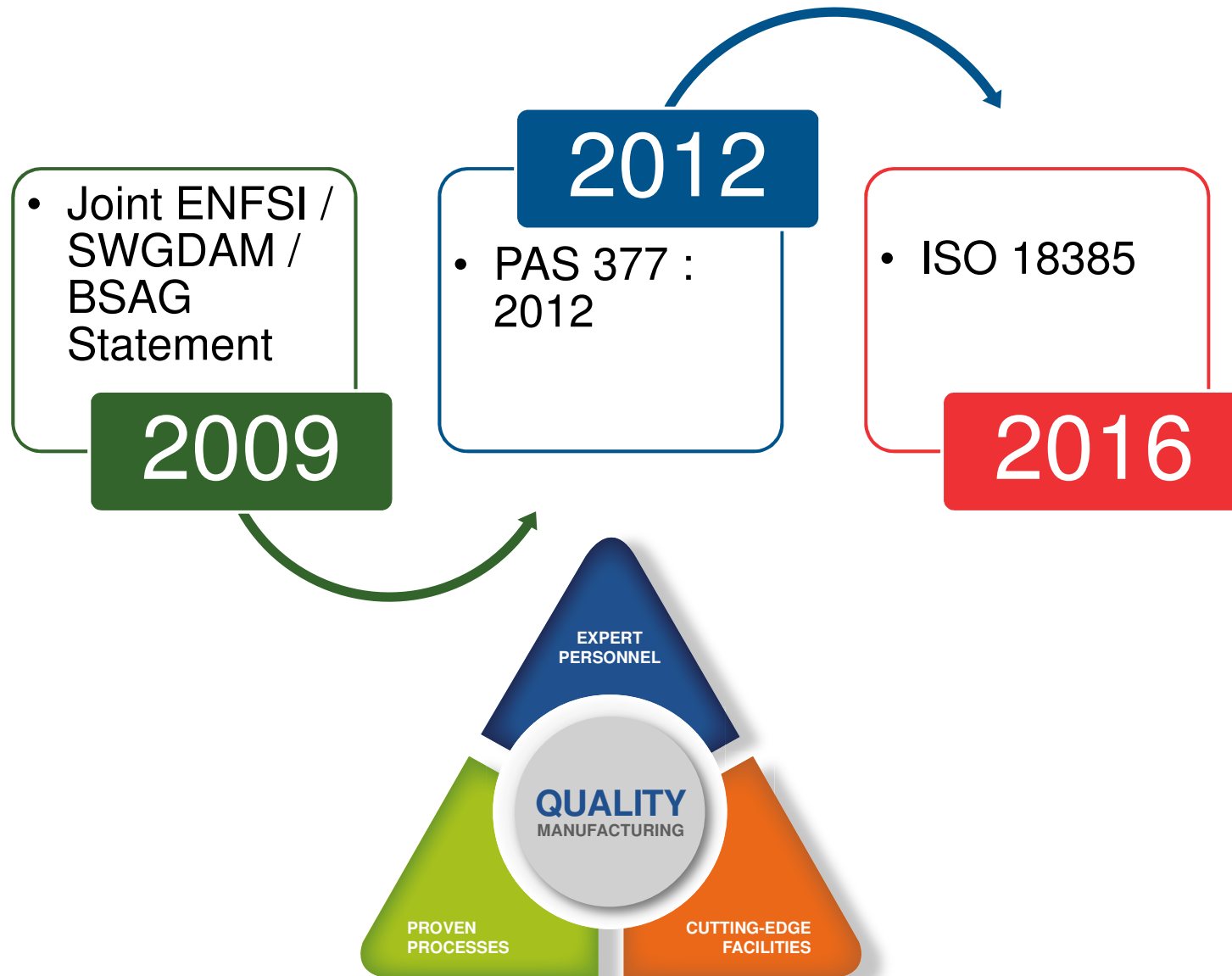
## ISO 18385 & Beyond: We're Serious About Quality



# What is ISO 18385? And Why is it needed?

- Global manufacturing standard
  - Aimed at reducing the risk of inadvertent contamination by manufacturers of consumables and reagents
  - Gives manufacturers the ability to label applicable products as “ISO18385 Forensic DNA Grade”
- Why is a standard needed?
  - Measurement equipment is becoming more sensitive
  - Forensic Labs are using more sensitive methods of analysis
  - Identifying lower and lower amounts of DNA during investigations
- What will be the benefits for the customer
  - Confidence in the product/manufacturer
  - Increased confidence in your conclusion
  - Reduction in wasted time/effort

# Thermo Fisher Journey to ISO18385



# Personnel

- Personnel at Thermo Fisher Manufacturing facility at Warrington are
  - Well educated
  - Well trained
  - Assessed for competence in all aspects of the work flow
- Proud to be able to support the criminal justice system, wherever in the world
  - Through the company's 4-I values Innovation, Intensity, Integrity, Involvement
- A number of staff have been recruited from a Forensic Background
  - Enabling a full understanding of the requirements of the work that is being performed

# Personnel



Stacey  
Quality Control Leader



Jo  
Manufacturing



Laura  
Quality Control Analyst



Kim  
Technical Support



Beccy  
Technical Support



Louise  
Manufacturing Leader

# Processes

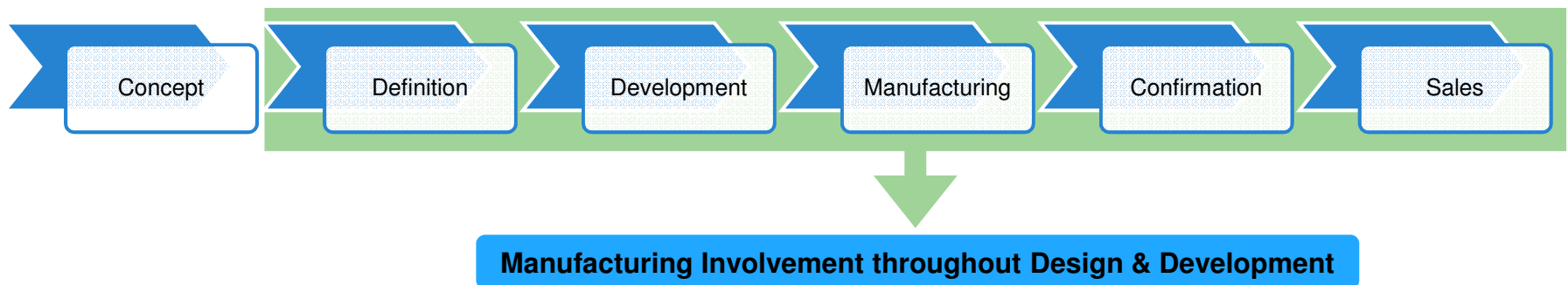
- Quality Management System
  - ISO 9001 – Since 1998
  - ISO 13485 - Since 2010
- Support for development and compliance to PAS377:2012
- Gowning
- One way personnel flow
  - Based on Risk assessment
- Elimination database
  - In place since 2011





# Processes

- New Product Introductions
  - Manufacturing involved during the early stages of development
  - Ensuring products are designed and developed with manufacturing quality and cleanliness at the fore front
  - Including Risk Management of the supply chain



- Quality Management Systems regularly reviewed and audited
  - Internal corporately
  - External BSI
  - Customers are openly invited to review



# Facility

- Investment in automation
- Designed to remove Human Touch Points
  - Reducing risk of hDNA contamination
- Areas are designed and upgraded to ease cleaning
- Validated cleaning process



# Assessment of Compliance

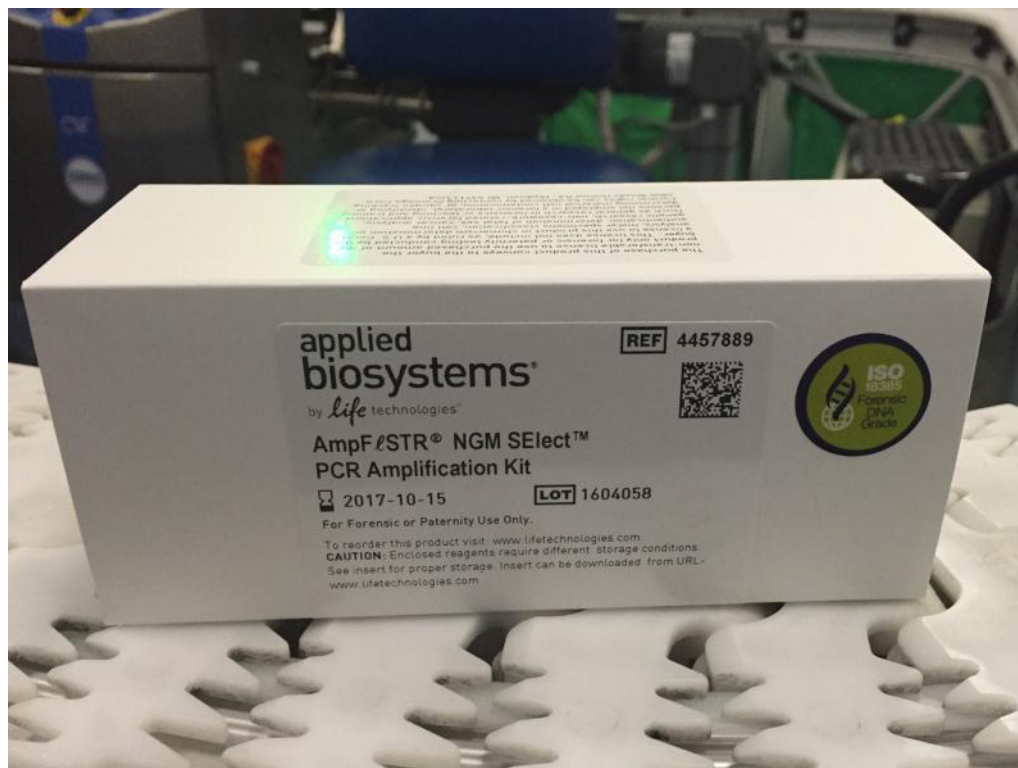
- So when we reviewed we were confident in our ability to meet the requirements
- It would have been easy to stop there, label and hope we were right
- But we didn't.....
- We enlisted an external, independent assessment – Kevin Sullivan



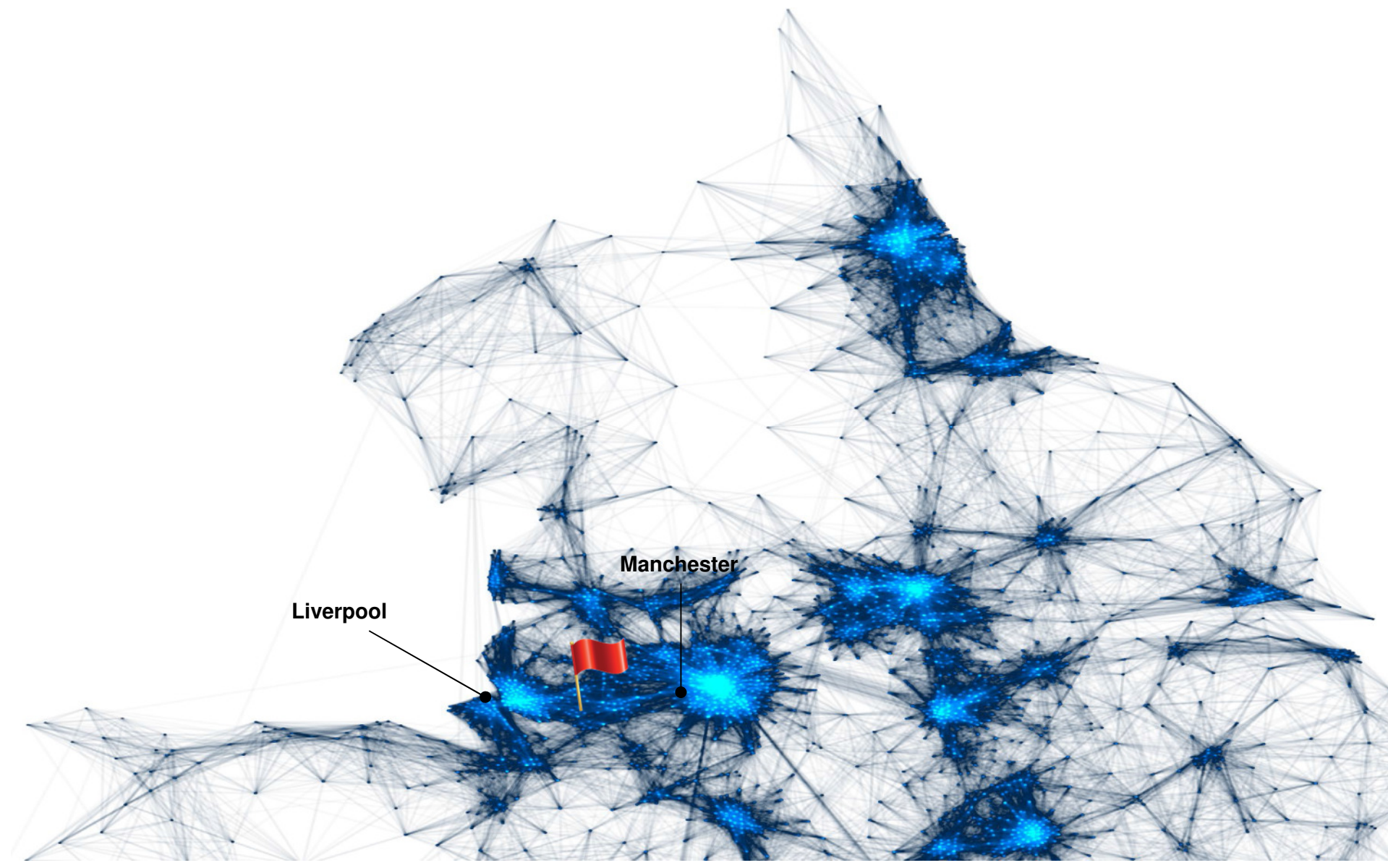
# What's next

- We are not going to stand still
- Compliance will be constantly assessed through internal audit program
- Any areas for further improvement are being followed up through the sites CAPA program
- Listen to you, the customer
- Expanded assessment program to other areas of business
  - Sample collection
  - Extraction kits

# Final Box Labelling

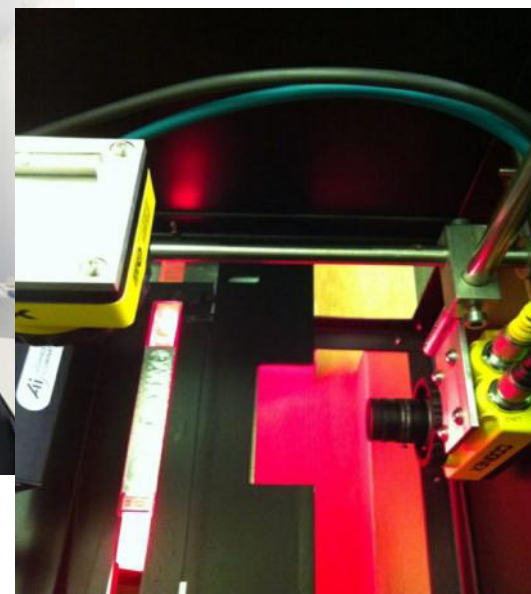


# Manufacturing





# Warrington Manufacturing Facility



Thank you!

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We're Serious About Quality