

The automated, integrated Lab of the Future

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What are the key elements of the Lab of the Future?



Automation

- Increase throughput
- Remove repetitive processes
- Free up resources



Rapid methods

- Faster time to results
- Smaller sample volumes



Integration

A connected lab
bringing the data from
all devices and
systems together



Digital

- Remove the paper
- Error prone, manual and time consuming
- Real time access to data



Lab of the Future: Manifesto: digital technology-based capabilities for the quality control (QC) lab of the future

What are the drivers?



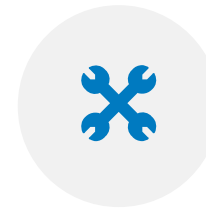
Efficiency

- Right first time – fewer deviations
- Reduce lead time for testing
- Visual, predictive analytics for continuous improvement



Compliance

- Increased Data Integrity
- Data is more complete and available in real time
- Enforce SOP's
- **Prevent most common deviations** and intervene when they do occur
- Demonstrable chain of custody



Technology

- Technology landscape is maturing
- **Increased adoption of digital and automation strategies**
- ***Lower total cost of ownership:*** Solutions do not require customizations

Digitalization

First you need to remove the paper

- Automate data collection from devices and people
- Eliminate redundant data entry and transcription errors
- Gain direct traceability of QC microbiology programs
- Increase worker efficiency
- Improve regulatory compliance
- Demonstratable Return on Investment
- Quickly advance green initiatives



Considerations for an electronic solution

What are your requirements?



Is it easy to use

Transition from paper can be met with apprehension so user experience and buy-in is key



Is it easy to maintain

Can you build your own test methods and workflows without coding and update them as needed?



Can you easily integrate with other solutions?

Integration with other lab devices and systems can be key to success for automated log entry.
Integration to equipment to automating acquiring data can save time and improve compliance

Considerations for a digital strategy

Ease of use for end user makes transition from paper easier



Follow the data

- What do you need to capture
- When in the process it is available
- **How do you need to use it, trending & investigations**



Detailed User Requirements

- When, where what data is collected
- How it will be used, how is it reported,
- Location based



Integration to other systems and devices

- The system should have the ability to seamlessly capture data from other sources



Reporting - Detailed User Requirements

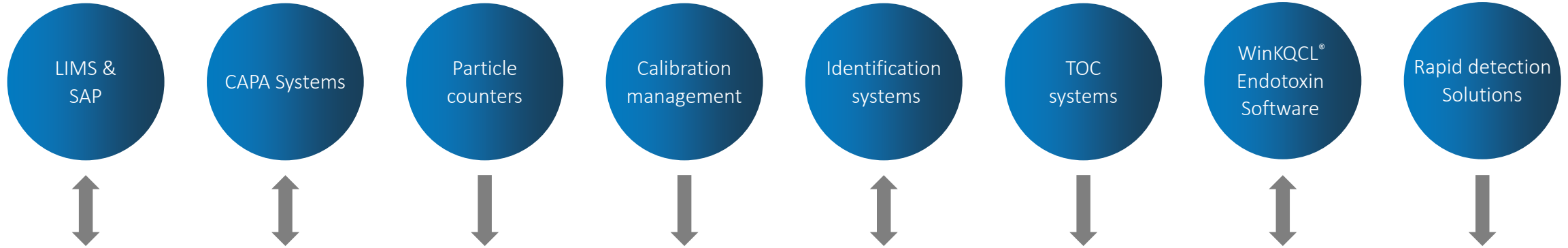
- Must be able to trend data – not specific enough
- The system should generate a report that includes a chart of sample results within a room or location for a specified date range and test method.
- The system should generate a report that includes a visual bar chart of the number of organism identifications per organism species, over a period of time for a specified set of Locations, Classifications and Organism Types.
- The system will allow for the generation of reports by utilizing sorting and filtering functions. For example by date range, sample type, sample status, above limit result, room (EM), system (utility) room classification, micro-organism etc.
- Ability to access data in real time to support investigations



Should make the workflows more efficient!

Integration

Bring all the data together



Automating data capture can reduce errors, improve compliance to regulatory guidance on data integrity and move to a review by exception workflow.

Automation

Reduce repeats and increase throughput with assay automation

- Improve efficiencies and reduce human error
- Accurately process large volumes of samples
- Deliver samples directly to the laboratory
- Reduce bioprocess development times and labor costs
- Reduce overall time-to-market for new biological therapeutics



Benefits of digitalization

Using your data to make informed decisions



Real time access to the data

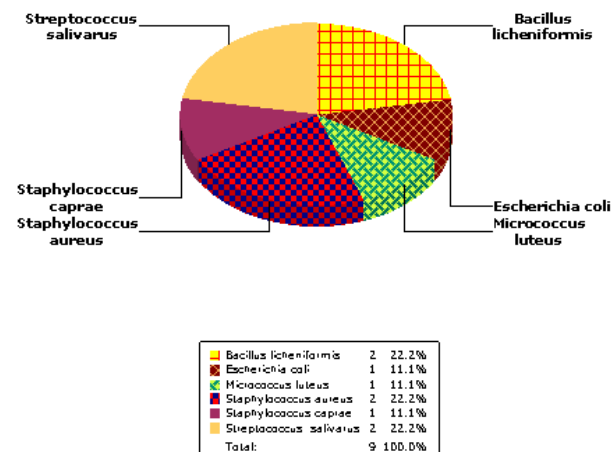
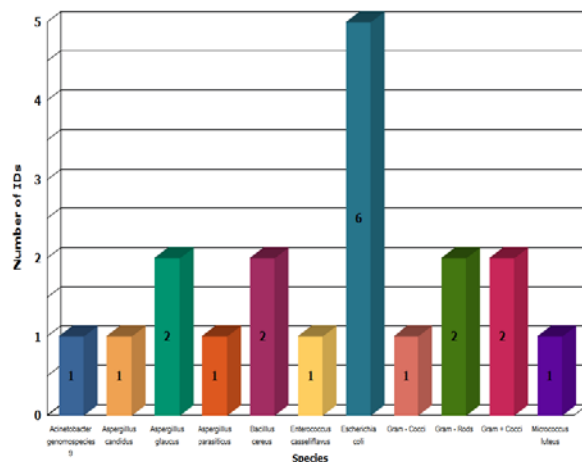


Ability to search data for investigations and trending and reporting



Ability to easily view your data on facility maps

Organism Description



Innovation

The robots are coming.....

- The project is a collaboration between University College Dublin (UCD) and industry partners – Lonza, PM Group, NIBRT, Novartis.
- The objective of the study is to develop a robot to undertake four key actions:
 - Pick and place sampling settle plates
 - Environmental surface sampling with contact plates
 - Viable air sampling
 - Particulate air sampling
- Grant from Enterprise Ireland
- https://www.cleanroomtechnology.com/news/article_page/Aseptic_manufacturing_The_robots_are_coming/161887



What is your strategy?

Lonza

Pharma & Biotech



Industry 4.0 and QC

- Emerging technologies will have a significant impact

- Automation, Rapid technologies, Robotics
Digitization, Advanced analytics,

- Challenge with QC is that organizations rarely develop, clear, long term, lab evolution strategy – requires investment and cost

- Advances in equipment connectivity – build this into requirements

- **First step is to have a strategic vision & roadmap**

Q&A session

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Pharma & Biotech

Any questions?

Please submit your questions using the questions pane at the bottom of your screen



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