University Hospitals of North Midlands NHS Trust

Implementation of an Electronic QMS – Lessons Learned

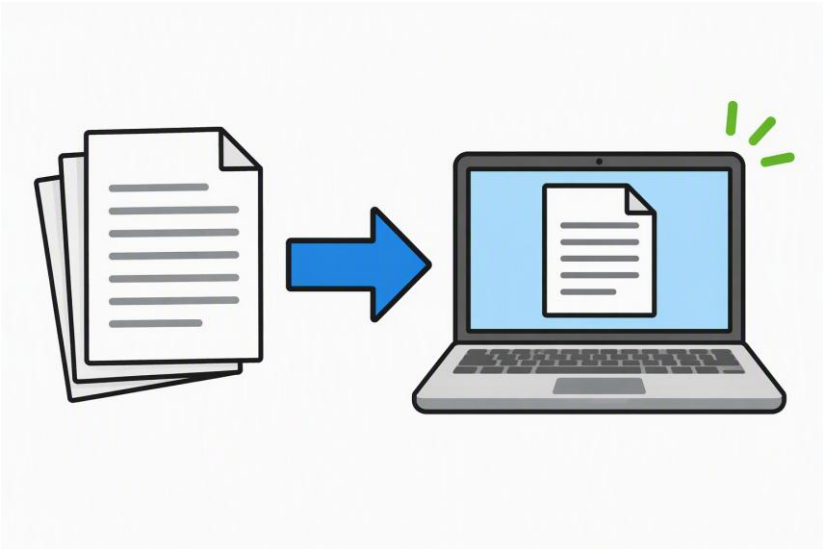
Aidan Rhodes
Quality Manager – University Hospitals of North Midlands



Kind Excellent Together

Background

- MHRA MS and WDA(H) licensed facility covering aseptic and SACT products, pre-packing, radiopharmacy and wholesaling
- Until 2024, the entire PQS was manual and managed using Microsoft Office and paper
- In October 2023 there was an opportunity to bid for NHSE National Monies to support English Manufacturing Units undertaking Classical Manufacturing and over-labelling/repackaging of medicines
- £90,000 was allocated by NHSE to UHNM strictly for the purpose of procuring an eQMS by April 2024



Procurement

- Extensive URS produced focussing on
  - Operational requirements
  - GMP compliance
  - Data integrity
  - Security
  - Validation and support packages
  - Compatibility
  - Backup and recovery
  - Business continuity
  - Cost and licencing structure
- Procurement, validation and implementation completed under change control

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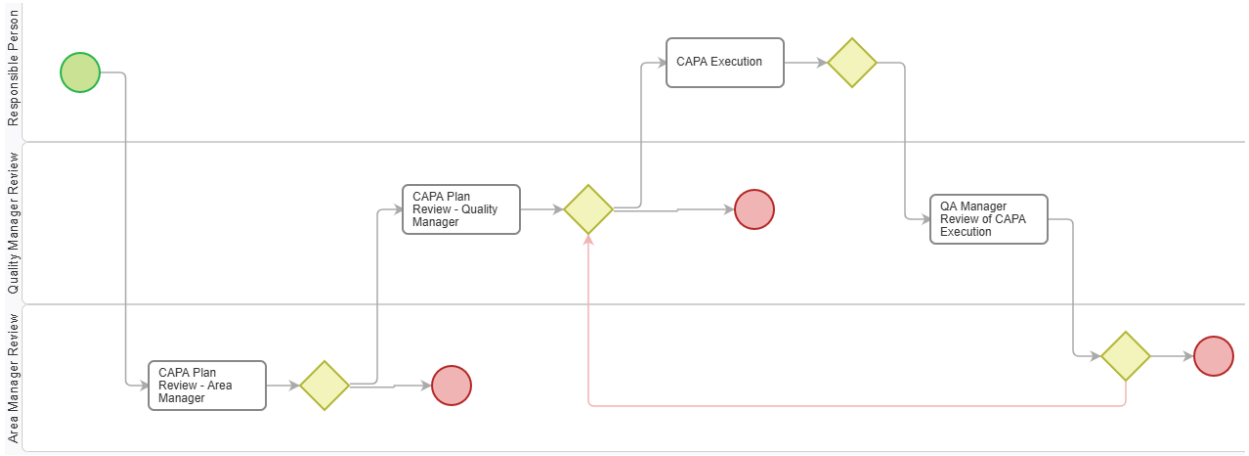
Procurement

- Multiple eQMS solutions evaluated
  - iPassport
  - Q-Pulse
  - Bizzmine
- Bizzmine met all mandatory requirements within the financial envelope, and all but one nice-to-have requirements



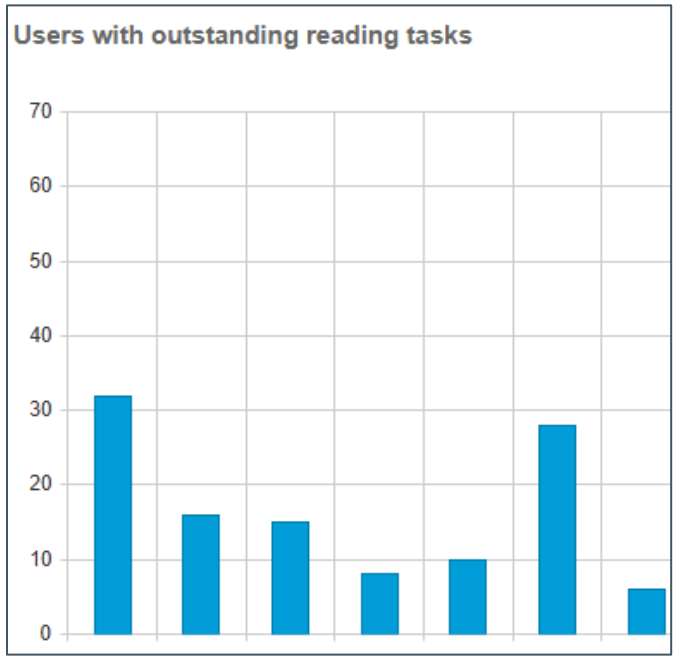
Why Bizzmine?

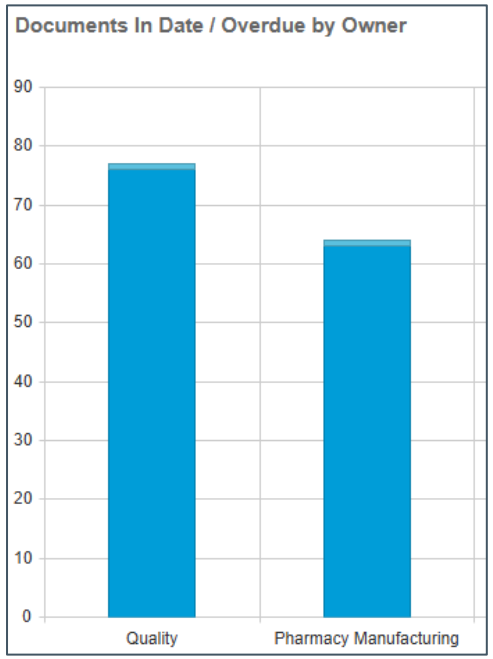
- In-depth customisation of workflows, data structures, forms, permissions, user groups
- Custom KPI dashboards
- Good support and vendor validation offerings
- Suitable licensing approach

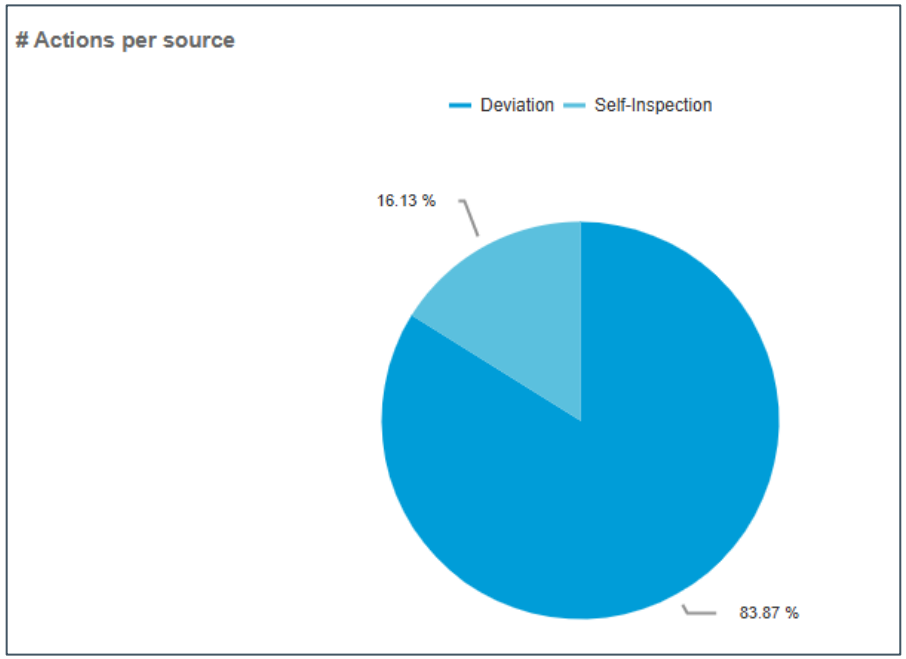


Custom Dashboards

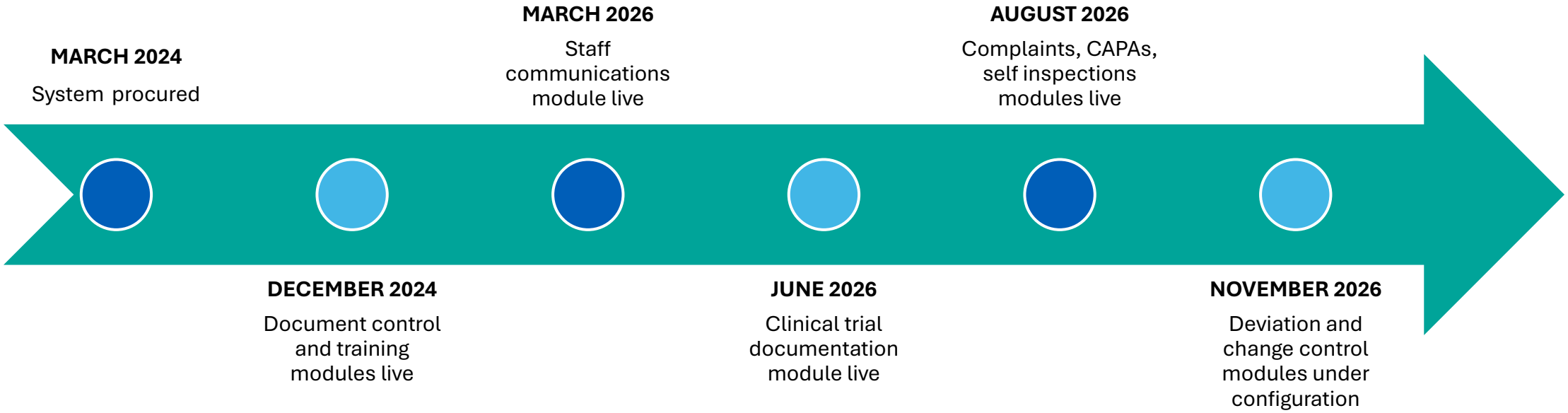
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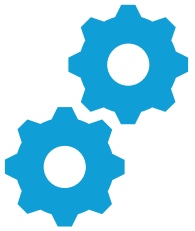
Implementation Timeline



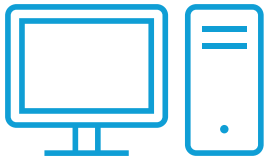
Key Lessons

- Start small
- Pick a date
- Maintain momentum
- Develop modules in house to reduce reliance on Bizzmine support
- Don’t be afraid to make changes

Start small



Take a modular approach. Start with the easy wins, simple modules and modules with minimal links to other PQS components



Get people comfortable using the system



Roll out to different staff groups over time

Pick a date

- MHRA inspection carried out June 2024
- Migration of training records onto an electronic QMS agreed as an MHRA action – target date end of December 2024
- Document and training module went live in December 2024



Maintain momentum

- It is easy to implement one module then go back to business as usual
- Important to keep chasing updates from provider and keep encouraging local engagement from the team
- Have clear responsibilities and ringfenced staff time
- We had a designated Digital Systems lead in the Quality team

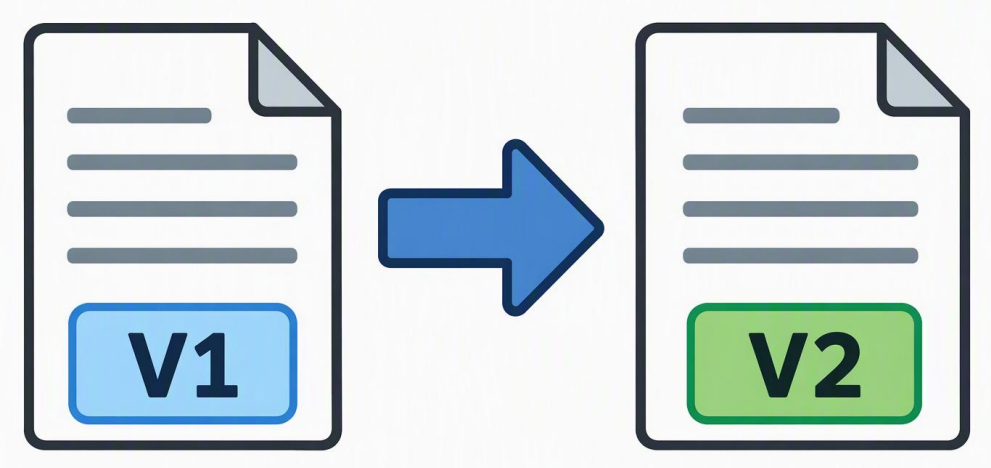
Develop modules in house to reduce reliance on Bizzmine support

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- Support team are there to configure your workflows, but it can delay the project
- UHNM system admins became comfortable with back-end configuration of modules
- We identified a potential to create a controlled staff communications workflow and had a working proof-of-concept after 1 hour

Don’t be afraid to make changes

- No matter how long you spend drafting and reviewing, you will want to change something about your workflows once you start using them routinely



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Benefits Delivered

- Reduced administrative workload
- Reduced paper usage
- Improved visibility of review dates and due dates
- Enhanced oversight and traceability
- Improved data integrity and process control
- Increased regulatory compliance
- Reporting into Quality Review meetings

Next Steps

- Complete implementation of outstanding modules
- Roll out across other service lines within Pharmacy e.g. Home Office Licence, GPhC Registered Pharmacy
- Share success across the trust for other users of Quality Management Systems

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Any Questions?



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Use of BD Cato® software at SGUH Aseptic unit

Uchenna Ihedioha

Pharmacy Team Lead, Technical Services

November 2026

gesh

NHS
St George's, Epsom and St Helier
University Hospitals and Health Group

Introduction

- BD CATO® is a novel, paperless, barcoded, volumetric / gravimetric system for the preparation and labelling of cytotoxic and CIVAS doses.
- Electronic replacing the requirement for paper worksheets in the clean room
- Automatically prints product labels at the end of product preparation, eliminating the requirement to manually print labels

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NHS
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Unique features of BD Cato® software

- Novel
- Paperless
- Barcode enabled technology
- Supports both Volumetric and Gravimetric workflows
- Maintains an audit trail of the preparation process
- Supports data Integrity
- Data retention / archiving

Pre- Installation challenges

- Availability of IT resource. Software required new server builds for both Test and Live environments.
- Configuration of hardware accessories – Balances, Cameras, Scanners
- Lack of widespread use within the NHS
- Trust IG approvals as personal identifiable data is processed via the HL7 interface
- Purchase of Bespoke isolators fitted with flat screen monitors, cameras and scanners
- Other accessories including clean room CPUs, Label printers, barcode printers, hand-held scanners, workstation computers, balances
- Capacity within pharmacy technical services – time & personnel
- Training
- Supplier support – BD Cato
- Obtaining Gravimetric data ie density, additive mass etc from manufacturers

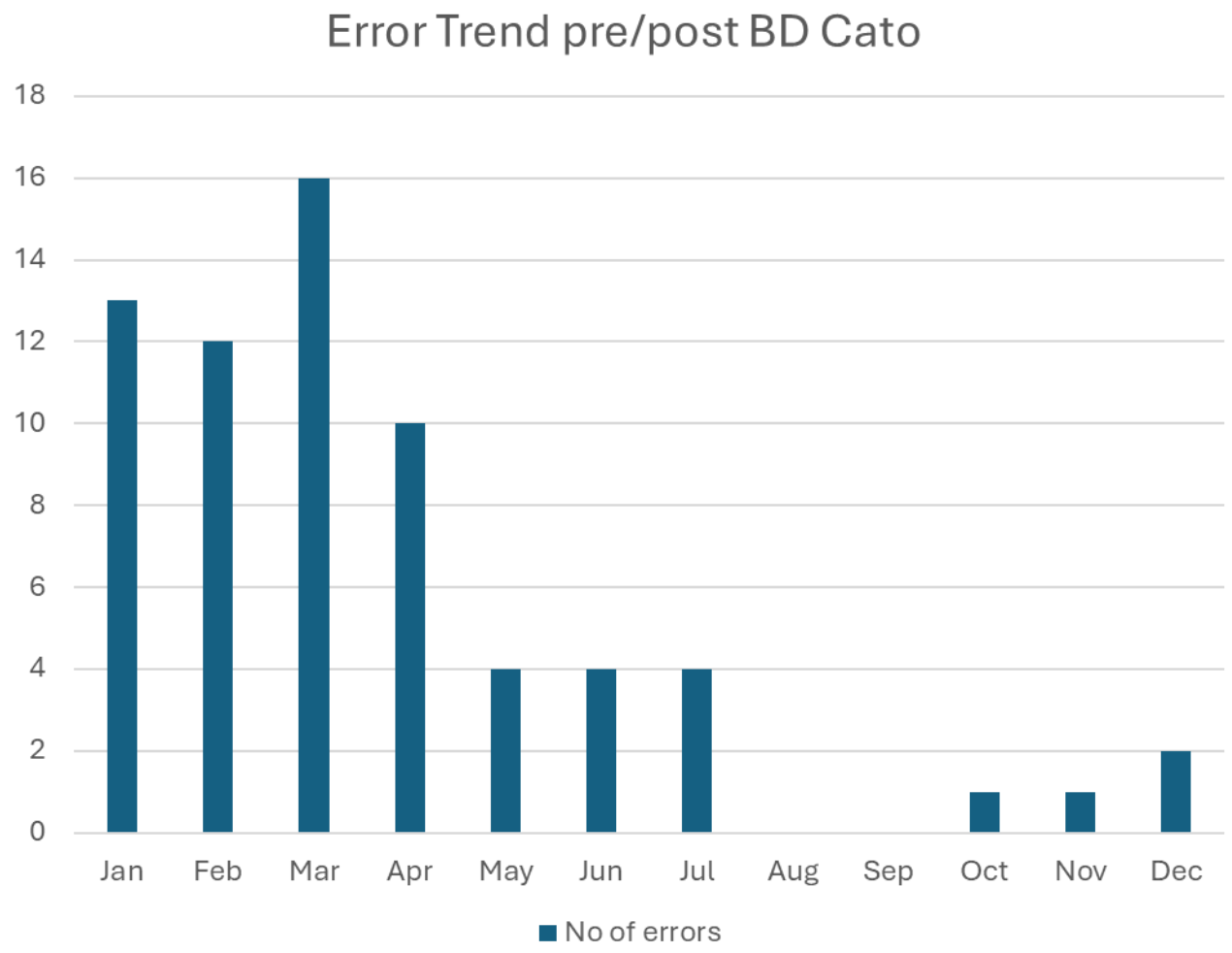
Post Implementation challenges

- Compatibility of software with Trust’s new operating system.
- Version updates require requalification.
- Communication from BD Cato on new version updates
- Training with staff changes
- Availability of IT support

Impact of BD Cato Software

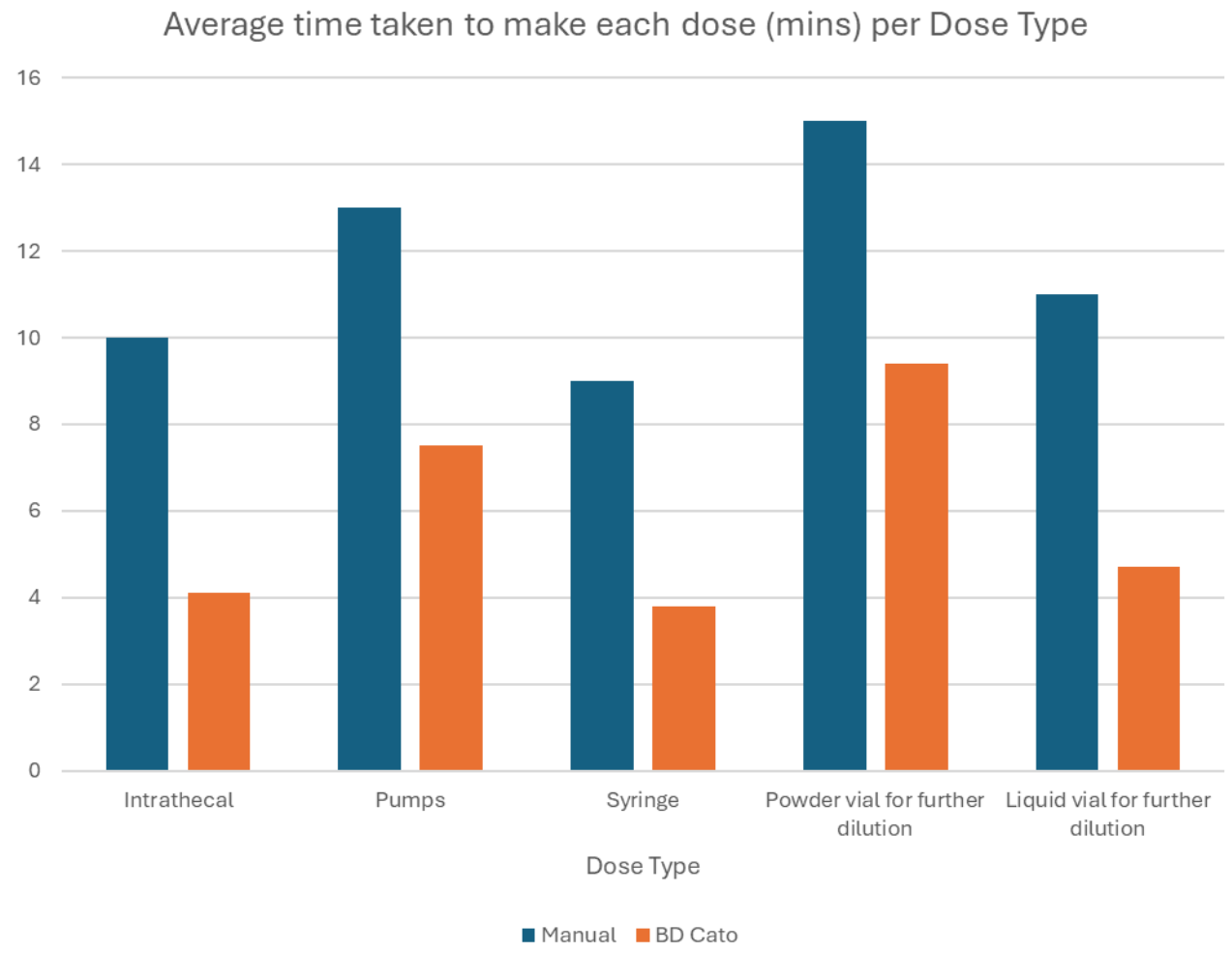
- Reduction / Elimination of errors

- Errors pre implementation of BD Cato were; Misspelling of patients' name, Drug name, Wrong route of administration, wrong expiry, wrong diluent and volume etc
- Error post implementation; Raw material batch number different from BD Cato allotted batch number



Impact of BD Cato software

- Improved efficiency - Improvement in product turnaround times from prescription input to final product release.
- Medication Safety- Gravimetric method far more accurate method of dose preparation over volumetric
- Cost efficiency- Paperless system
- Capacity- Enhancement in available capacity following reduction in product turnaround times



Other Benefits using the BD Cato® software System

- Inventory Management – *Lot management has helped to reduce waste*
- Reduction in risk of microbial ingress into clean rooms – *Following elimination of paper*
- Data Integrity – *BD Cato maintains an audit trail of any entries made to patient records. Raw material entries once used to prepare patient doses cannot be deleted or altered.*
- Audit trail – *The camera automatically takes pictures of each step of the compounding process which can be used for remote verification and documentation. The photos alongside other records are archived.*
- Data retention / archiving – *Patient therapy data cannot be deleted and is held on the system forever.*

Learning from Implementing BD Cato®

- The Implementation was impacted by Covid
- Trust IT must be involved when making a business case for any future software purchase as IT resource is critical
- The absence of a network of users within the NHS was a challenge. We had to initiate one with the lone NHS Trust using a limited feature of the software and a private hospital, to be able to exchange data and share learning.
- Manufacturers had to be approached directly to provide gravimetric data, and even at that some were not forthcoming, referring you instead to what was available on the SPC.

Questions

Thank you.

For any other information, please see:



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