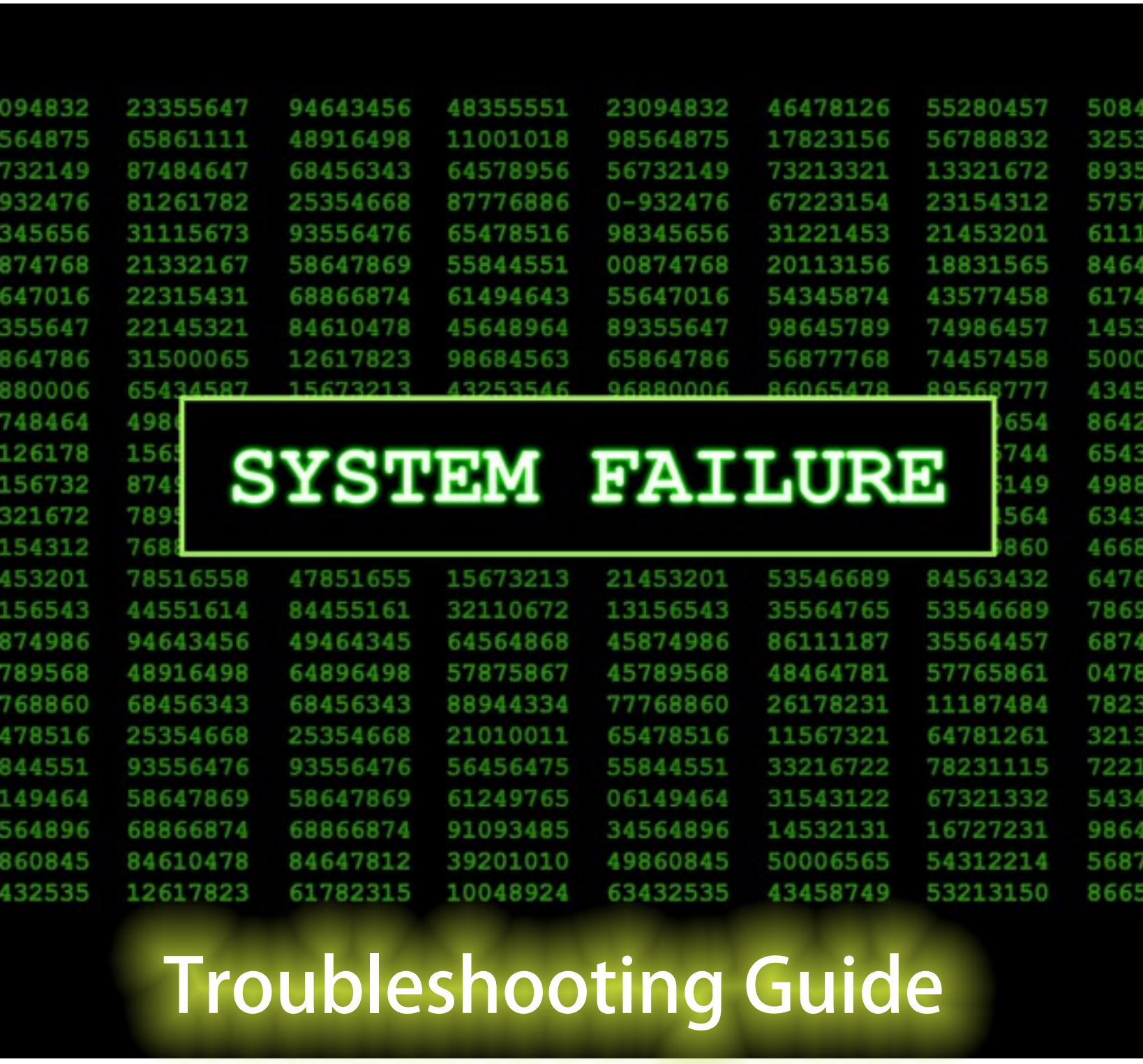
Compound & Biosample Management

IT Issues In Sample Management



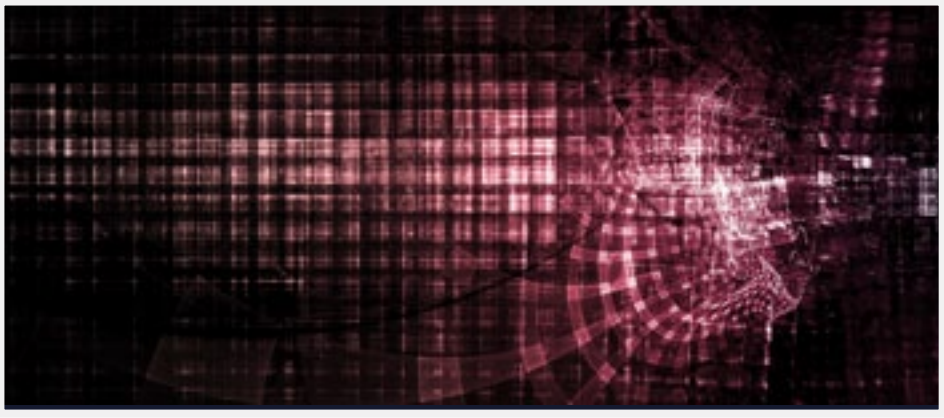
Troubleshooting Guide

Pharma iQ
a division of IQPC

Successful compound management and biological sample management stand as key enablers within the drug discovery process. Computerized inventory systems and sample cataloguing make the use of IT equipment and fluid collaboration between hardware and software critical to both divisions. However, various systems in the pharma industry can speak in conflicting languages which complicates communication and data exchange in various verticals including in compound and biosample management. Various organisations have arisen to help standardise and champion interoperability through setting criteria.

Compounds of a high integrity contribute to reliable results when locating drug candidates. Compound rejections are said to have been lowered in number through the use of automation within compound management processes and high throughput screening. In a recent report Kalorama Information added: "With the high cost of bringing a drug to market, lab automation streamlines drug discovery and research labs' processes, eliminates downstream bottlenecks and speeds target identification and screening. The need to undertake large-scale assays cost effectively makes automation a fundamental requirement in biomedical research as well as drug discovery." [9] The global lab automation market is projected to reach $5.052 million by 2020, with compound management standing as a segment of this market.[10] Lab automation is seen as a key way to return both time and money to compound management departments. Therefore, having sufficient automation technologies to handle and preserve the quality of samples and provide timely access to samples are at the heart of compound management.

According to the Global Biobanking Market Report "….automating biobanking workflow will benefit biobanks by maintaining integrity and quality in long-term samples, minimising manual errors, improving the workflow efficiency, and enabling long-term cost-effectiveness. "Automation minimises manual errors such as mislabeling or inaccurate sample



barcoding and improves the technical efficiency. Further, it plays a vital role in blood fractionation, DNA extraction, labeling, and capping techniques."[1]

IT failures have the power to incur large financial costs and productivity costs. Work could be jeopardised when compounds or biological samples can't be retrieved when needed for experiments or screens that have taken up a lot of preparation time.
In our 2016 Activity tracker report, automation was seen as a priority and an investment must. Compound management respondents stated that system maintenance & automation stood as predominant challenges for them to tackle.

Just over 30% of the compound management and biobanking respondent bases stated that automation, robotics, new tech and new system upgrades were on the cards for 2016.

Innovation and next generation software and technologies are perceived as big topics faced by the industry at the moment with some firms evaluating their strategies and the potential impact on workflows and processes which are vital to the operation of automation. Keeping up with the market's evolution is seen as the most prevalent reason to seek and achieve next generation innovation within compound management.
On this subject Marybeth Burton, Director, Discovery Compound Management Merck Research Laboratories said: "It's critical, in my estimation, for enabling proactive management of compounds in the drug discovery arena, and it's very important to enable agility and flexibility so that you can [stay] current with evolving stakeholder needs."
Limited budgets can mean that needed upgrades or replacements for aging compound and biosample IT systems can't occur as quickly as hoped. As market practices advance, companies are faced with different options from outsourcing to investing in new technologies in order to maintain momentum.

However, the balance between the mounting pressure to control costs in drug discovery with maintaining production rates, efficiently coordinating comprehensive libraries and working out how best to store them: remains a complex task for the industry as collections expand.
Cost scrutiny has called for better decision making with investment spend especially with IT systems. This troubleshooting ebook will explore aspects to consider in your decision making..

IT issues in sample management Trouble Shooting

Troubles

Having appropriate systems: It can be a challenge to have appropriate systems with all the necessary functionalities – to log samples, track samples and input data associated with the samples, etc. Although, there are commercially available systems, a gap still needs to be filled in fully to provide for all the IT needs within sample management.

In-house systems provide extra flexibility but can lack visibility: Chris from Medimmune noted that due to the size of their human sample collection they have been able to build in-house simple sample managements structures for their human biological samples. However, he continues that being without a system can cause complications depending on the number of samples in regards to tracking and tracing the samples and their destinations.

Solutions

Be proactive - work out your scope upfront: Develop the scope upfront to reduce the number of changes to a system to fit requirements and expectations are established and fully understood. This may entail the initial defining of a database, system or a problem to be solved.

Know what you need and what you don't need: Elizabeth Admirand of Epizyme notes that every group will have a list of 'must haves' and a list of 'nice to haves.' The 'nice to have' list is where you can be more cost effective in order to guarantee that you get all of your 'must have' items. Be sure to communicate everything. Make sure that the stakeholders in these decisions understand where you are coming from so they can put everything into perspective with the corporate objectives.

Troubles

Limited longevity in developing in-house: Some firms lack the resources and IT infrastructure in-house to develop the sample management software and maintain them as libraries grow and evolve. Therefore, in these cases processes have to be adapted to work within commercially available solutions.

Elizabeth Admirand highlights that when there are millions of compounds to process, a sound automation and IT set up is needed which is in sync. Those libraries are likely set in stone in terms of formatting and processing, leaving little room for flexibility—which can be beneficial in terms of an IT stream.
When working with smaller sets that flexibility becomes a key bonus to the company because libraries can be used in different ways. In those cases, perhaps automation is not needed to be online with the system, but if it is, significant programming knowledge will be needed to programme streams properly and avoid losing precious time.

Solutions

Understand the capabilities of your systems: Sue Holland Crimmin in an article for Pharmaceutical Outsourcing.com notes that knowing the capacity of your IT system is a vital step. It was found for example longer cycle times had a direct relationship to capacity used:

"Extended cycle times are caused by fluctuations in workload (or resource availability); as capacity utilisation is increased the backlog due to peaks takes longer to clear. In CM processes where cycle time is important but not critical, plan on working below 75% capacity on average.CM has had a good track record of introducing and exploiting technology within drug discovery. Here again judicious cost containment and maximising ROI is necessary."[3]

Get industry stakeholders talking about what's important in software: Chris notes that the industry could see real value from gathering interested parties, be they biopharmaceutical companies, academics, suppliers to finalise and agree the base requirements from a biological sample management system. With the aim to produce a unified approach to biological sample management systems and the functionalities required.

Troubles

Integration of old and new systems: It is common among many companies to outgrow systems that legacy work has been stored in. It can be quite difficult to find one system that can handle all needs and caveats, which is why many companies end-up developing homegrown solutions. This ends up placing limitations on taking advantage of new developments and advancements, as the firm still has to capitalise on investment embedded into existing structure. Cutting edge tech may provide access to enhancing storage, collection and analysis methods.

Aside from obvious financial concerns, interactions between old and new systems can be blocked by incompatibilities, stubborn workflows, processes and data definition types. [7]

Open innovation vs structure: Structure causes a dominant IT hurdle regarding open innovation in sample management. A firm will not want its science to be hindered by too rigid of an infrastructure, but process can't change all the time. Every time something changes, especially in compound management, there is a lot of validation that needs to be done to ensure it isn't causing problems down the line. Knowing and communicating the balance is essential to making open innovation work.

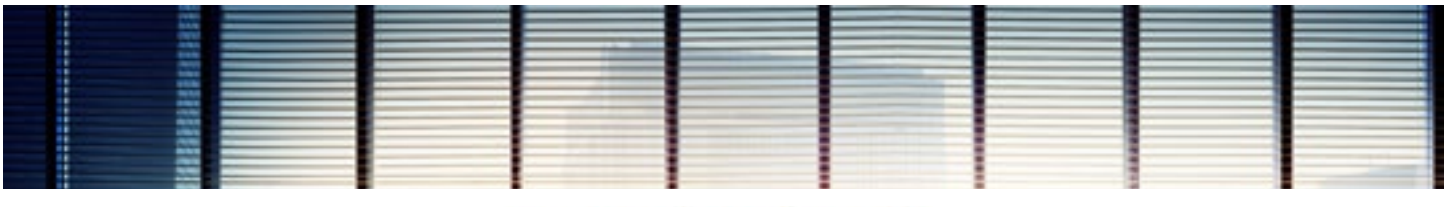
Solutions

Interoperability testing to find issues: Some providers have interoperability specialists to run tests on equipment and systems in advance of real life use

Working with solution providers / experts to extend life of tech: Collaboration with vendor experts is instrumental to making sure that a systems full capacity and shelf life is reached. ROI can be upped by adding new bolt on functions instead of replacing with new systems [3.]

Smarter Maintenance Schedules : Awareness and know how with automation and engineering will be needed for part replacement, spare part management and coordinating productive preventative maintenance plans. These can help build quality SOPs top add to tech shelf life.

The advantages from predictive maintenance through the internet of things is thought to have the potential to yield savings of up to: 12 per cent in line with scheduled repairs, lowering general maintenance costs by up to 30 per cent and eradicating breakdowns of up to 70 per cent.



Troubles

Dry sample dispensing limitations: With uncharacterised vials, the process for dry sample dispensing can encounter errors, David Booth of Titian Software London mentioned in an article that users had reported that under half of dry compounds suit these devices.

Lack of linkage: Attached to quality concerns with historical biosamples, Amanda Maxwell in a recent article for Thermofisher noted a study where staff struggled to find files linking sample identity to patient identity. [6]

Merging physical data gained through automation : Research commissioned by Pharma IQ found the main issue sample management professionals experienced when integrating sample information and discovery data was merging physical data gained through automation.[1]

Solutions

Use of Volatile solvent transfers
Volatile solvent transfers are useful for combatting dry sample dispensing limitations. Here the powder is solubilised in the container, liquid dispensation is then used and then the solvent is removed. This does have the risk of concentration inaccuracies due to residue on the side of the container in the evaporation but the process does allow more compound samples to be dissolved in a fully automated manner according to David Booth.

Lack of linkage – culture solution
To avoid disconnect between sample identity and patient identity staff should be instructed to ensure they stick to necessary data recording practises for identification of all biosamples.

Also as data sharing is required for all study proposals, biorepository staff should be proactive in making sure that researchers ensure information is made available promptly.

Solutions

Microchip tech so samples can be kept with their data at all times
There is microchip hardware available in sample containers so that the data is paired with a sample at all times. RFID tags can hold more data than barcodes and are capable of being read at very low temperatures, making them suitable for biobanks.[7]

Aim for one master data layer:
Instead of having isolated solutions with various databases attempting to communicate with each other, compound management firms should aim for one master data layer. This can provide a more modular approach to data and process handling and a higher level of transparency to customers allowing for a snapshot of the project life cycle of the compound to be communicated to users.[3]

Make the retrieval process more transparent to avoid duplication:
Sample workflow and ordering transparency will be helpful with the exchange of compounds between centers.[7] These efforts will prevent scientists from doubling orders by making processes more transparent, allowing the user to see where their compounds are. Carsten Aprill, Head of Compound Management AbbVie Germany adds:"…that will make our lives easier, not only for compound management, but also for whole R&D, because then scientists can focus on science and not on compound logistics."

Don't get too obsessed with the robots: Remember, for all its benefits, automation is not the only silver bullet that can improve drug discovery. The removal of redundant processes and the physical and human elements must also be enhanced

Collaborate, maximise quality, develop effective data management and capitalise on outsourcing for cost effective compound management and biobanking

Reasons to Attend:

- Discover new IT solutions and overcome integration challenges with a Case Study from Pfizer.
- Make important decisions about outsourcing vs. insourcing based on cost analysis with insider tips from Johnson & Johnson.
- Acquire new strategies for automatic weighing to save you time and improve quality with expertise from GlaxoSmithKline.
- Examine crucial patient data utilisation regulations in the EU with advice from Sanofi.

www.samplemanagement.iqpc.co.uk

Call: +44 (0)207 036 1300 | email: enquire@iqpc.co.uk

Download Agenda

Research
1. http://www.compoundmanager.com/integrating-compound-management-analytical-and-automation-workflows-to-contribute-to-drug-discovery-success-mloc-f-ty-m/Addtional=true#
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4. http://www.biostorage.com/blog-posts/sample-management-challenges-and-opportunities-in-asia-pacific/
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