POST EVENT PROCEEDINGS

SmartLabs Automation 2023

20 - 21 March 2023 | London, UK

Oxford Global was delighted to invite you to attend our **Pharma Automation & Robotics Congress**, consisting of the **2nd Annual Pharmaceutical Mobile Robotics Congress** and **Smartlabs Automation & Robotics Congress**. You engaged with esteemed pharmaceutical & biotech representatives as well as thought-leaders from academic & research institutions onsite and benefited from attending over 40 presentations. We welcomed 200+ delegates for two days of cutting-edge scientific sessions and case studies on advancing the development of pharma logistics & automation, plug and play robotics, digitalisation of labs and automation & process optimisation in R&D labs.

We are delighted to present you with concise and insightful summaries of presentations delivered by prominent thought leaders in this comprehensive post-event proceedings document.

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CONTENTS

Day 1 Track 1 Accelerating Digitalization in QA QC Labs, Automation & Process Optimisation in R&D Labs

Digitising Analytical Methods – The Methods Hub Project

Azzedine Dabo & Birthe Nielsen

The Methods Hub Project, an initiative within the Pistoia Alliance, is a not-for-profit organization that operates in the pharmaceutical ecosystem and boasts approximately 200 members from various sectors. The primary objective of this project is to address interoperability issues between proprietary hardware and software systems in the pharmaceutical industry by digitizing and standardizing analytical methods.

One of the main challenges faced by the project is the seamless and efficient transfer of analytical methods, particularly high-performance liquid chromatography (HPLC) methods, between different vendor systems. Currently, these methods are manually stored in text-based documents, leading to reduced efficiency, diminished reproducibility due to varying terminologies, and limitations in cyber resilience.

To tackle these issues, the Methods Hub Project has developed a sophisticated Methods Database that utilizes the Allotrope Data Format (ADF) and RDF graph model to establish standardized terminology for HPLC methods. Additionally, the project has created adapters tailored for different chromatographic data systems, such as Agilent OpenLab and Waters Empower, which facilitate the conversion of methods from one vendor system to another. These methods are then stored in a centralized Methods Database, streamlining the data transfer process.

In successful demonstrations, the project showcased the seamless transfer of methods and results between different instruments within the same company and even between two different pharmaceutical companies, GSK and Merck. Furthermore, they displayed the overlaying of data from various operating software and hardware to demonstrate the robust interoperability and data transfer capabilities of the Methods Database.

Although the project is still ongoing, it appears to be making significant progress. There is a call to action for interested companies to get involved in implementing the Methods Database, indicating an openness to collaboration and partnership. Becoming a member of the Pistoia Alliance would likely provide companies with access to participate in and benefit from the continuous advancements of the project and its potential solutions for the industry's analytical method challenges.

Overall, the Methods Hub Project's efforts hold promise for enhancing efficiency, reproducibility, and data management in the pharmaceutical sector.

Automating The Lifecycle Of A Purification Sample In Drug Discovery

Holly Douglas

The presentation focuses on how AstraZeneca is leveraging automation to optimize the entire lifecycle of a purification sample in the drug discovery process. The speaker begins by providing an overview of AstraZeneca's separation sciences department, which plays a crucial role in purifying compounds synthesized by chemists before they proceed to the testing stage. With three teams across the UK, Sweden, and the US, they support over 200 internal chemists and handle around 15,000 final compounds annually.

To manage the large amount of data generated from thousands of samples, AstraZeneca has established a robust global data infrastructure. This infrastructure includes a cloud-based analytical database where all instrument data is stored. The data is tagged and categorized based on its type, such as screening data or preoperative data. Standardized metadata fields ensure consistent information storage. Chemists and analysts can access and reprocess the data using ACD Labs, extracting metadata to track trends and monitor instrument performance. This ensures the data is findable, accessible, interoperable, and reusable (FAIR principles).

One key aspect of automation discussed in the presentation is the automated data processing of chromatograms. Since multiple chromatograms need to be assessed for each sample, AstraZeneca employs software that can handle data from different instruments and vendors. The software, such as Maestro Labs' Best Method Brick or M-Gear software, analyzes various criteria like resolution, purity, peak shape, and retention time to determine the best purification method. The software generates a method summary with scores for each method, allowing analysts to review and select the optimal approach. A script uses the metadata and chromatographic data from the chosen method to create a sequence for sample purification. This sequence, including information like stationary phase, gradient, and molecular weight, can be directly uploaded to the purification instrument.

In addition to data processing, the automation of sample handling is another area of focus. AstraZeneca has developed a custom solution using a sensor robot to streamline post-purification workflows. The robot incorporates features like barcode scanning, on-the-fly calculations, dissolution checks, and the ability to prepare NMR and LCMS samples. It enables the precise tracking and efficient handling of samples, minimizing manual errors and saving time for analysts.

The presentation also addresses the importance of sample tracking throughout the entire process. AstraZeneca is currently trialing software that allows direct sample submission from chemists' electronic notebooks. This software aims to automate the generation of screening sequences, facilitate batch processing, and provide a detailed sample status visible to both purification scientists and chemists. It also ensures that the generated reports are readily available for integration into the chemists' ALM system.

Overall, the implementation of automation in data processing, sample handling, and sample tracking significantly improves efficiency, accelerates project progression, and enhances data flow within the purification sample lifecycle at AstraZeneca. By reducing manual effort, enabling faster decision-making, and ensuring accurate sample tracking, automation plays a crucial role in optimizing drug discovery processes.

Journey Towards The self-learning analytical lab

Johan Ulander

The talk titled "Journey Towards the Self-Learning Analytical Lab" focuses on the development of an analytical AI program in the field of pharmaceutical sciences. The speaker's team works across the entire value chain of pharmaceutical development, from early drug discovery to product development, and aims to enhance efficiency and knowledge sharing within the field.

The speaker mentions that their team is part of the Data Science and Modeling department, which started about four years ago with only three members and has been steadily growing since then. They provide support to various areas of pharmaceutical development, including quantum computing, imaging, and knowledge graphs. The specific focus of the talk is on analytical AI, which the team has been working on for the past three years.

In the early stages of their work, the team realized that analytical chemistry is a vast field with various applications and purposes within pharmaceutical development. They also observed common pain points and inefficiencies in the analysis of results, such as manual data handling and information flow constraints. Their vision was to create a system that could provide insight, recommendations, and efficient workflows across the entire drug development process.

The team started an analytical AI program with the goal of enabling analysts to have better insights, remove bottlenecks, and spend more time on scientific work rather than administrative tasks. They aimed to create an AI system that could interpret experimental outcomes, generate labeled data, and continuously learn from new information. The system would assist in experiment selection, execution, and result

interpretation, while also allowing analysts to provide feedback and improve the AI's performance.

To achieve their goals, the team focused on augmented LCMS (Liquid Chromatography-Mass Spectrometry) evaluation, method optimization, and computational divisions. They also explored the implementation of automated workflows and collaborated with commercial companies to integrate their solutions.

The talk further mentions the team's work on automated solubility assessment and the use of imaging analysis to determine if components are in solution. By leveraging cameras and training AI models, they aimed to reduce the number of manual steps required in solubility assessment.

In addition to separation science and method optimization, the speaker briefly discusses their team's efforts in degradation analysis. They highlighted the importance of stability and impurity analysis in drug formulation and risk assessment. The team utilized efficient experimentation methods and aimed to transform the large amount of data generated into knowledge that could help predict degradation patterns and make informed decisions.

The speaker concludes by emphasizing the transformative potential of their work, both in terms of efficiency and technical success. They advocate for increased utilization of analytical data and the adoption of standardized formats to enable better data analysis and knowledge sharing across the industry. The speaker also highlights the significance of cross-functional collaborations between data scientists, analysts, and researchers in achieving these goals.

Throughout the talk, the speaker acknowledges the contributions of various individuals and teams involved in the project, emphasizing the collaborative nature of their work.

One Step Closer To SmartLab – Slope UV Spectroscopy Feasibility Study

Jufang Wu Ludvigsson

The presentation begins by discussing the introduction of new technologies to the QC lab. Three approaches are outlined: integrating new technology during the technology transfer stage, introducing innovative technologies through the high-performing lab partner, or adopting new technologies through local equipment purchases. The presenter emphasizes the importance of harmonization and standardization, which can lead to improved knowledge development, installation of new technology platforms, and a more efficient work environment.

The focus then shifts to Solo VP, a slope UV spectroscopy technique. The presenter explains that Solo VP uses pass lenses to collect multiple absorbance data points and calculate a slope regression. This technique eliminates the need for standard preparation and sample dilution, resulting in faster analysis and reduced experimental errors. The wide concentration range of 0.1 to 300 milligrams per milliliter makes it suitable for in-process control tests.

The presenter shares the methodology and results of the feasibility study conducted with Solo VP. The study examined small molecule compounds and protein formulations. In the case of small compound oral solutions, discrepancies in the measurements were observed due to the presence of hydroxypropyl betacyclodextrin, an excipient with UV absorbance. Baseline correction and determining the extinction coefficient value for each concentration were identified as necessary steps for accurate measurements.

To evaluate Solo VP's applicability to protein formulations, drug substance solutions and drug products were tested. The results demonstrated linearity, accuracy, and precision across different concentration levels. Comparisons were made between Solo VP and traditional UV measurements using Agilent Cary 60, revealing comparable results. The study also examined different vessels (plastic and quartz) for sample measurements, and similar outcomes were observed.

The presenter concludes that Solo VP is user-friendly, with easy instrument installation and software usage. The instrument requires routine checks and provides fast UV spectra measurements within one minute. Concentration measurements can be obtained in two minutes without the need for time-consuming standard solution preparation or sample dilution. The study suggests that Solo VP has potential as an inline technology for in-process control during formulation development and manufacturing processes.

However, a question is raised regarding interference from cyclodextrin and other excipients that may bias the results. The presenter acknowledges the concern and agrees that additional method development and validation would be necessary for accurate analysis when excipients are involved. The application of Solo VP for in-process control is acknowledged as beneficial, but careful consideration must be given to address interference issues and ensure accurate measurement of the API.

End-To-End HTE In Process R&D- Towards A Self-Driving High Throughput Robotic Lab.

Steven Fussell

The speaker explains that the goal is to develop a self-driving lab that operates 24/7, integrating high throughput experimentation and machine learning, to accelerate the development of medicines and reduce costs.

Process research and development are focused on developing and manufacturing the active drug that goes into the formulation process. Medicinal chemistry roots are inherited for synthesizing small quantities of material, which need to be transformed into commercial processes for synthesizing larger quantities, supporting regulatory filings.

The traditional development of new medicines takes a long time and costs billions of dollars due to increased molecular complexity and elongated clinical trials. The objective is to improve speed, quality, and cost-effectiveness to make medicines available faster. High throughput experimentation plays a crucial role in process research, identifying optimal synthetic strategies to make molecules and efficient chemical processes for large-scale manufacture.

Implementing high throughput experimentation allows for rapid exploration of chemical space by running multiple reactions in parallel, leading to quicker decision-making regarding process viability. Automation and robotics have been employed to accelerate the generation of fundamental data, allowing scientists to focus more on thinking and analysis rather than physical preparation of experiments.

The combination of computational calculations with high throughput experimentation and machine learning helps predict unexplored conditions and identify optimal reagents for chemical transformations. The development of end-to-end robotic platforms and digital connectivity between software and hardware elements is crucial for achieving a fully automated and integrated self-driving laboratory.

The automation of LCMS data readout has been successfully achieved, improving efficiency and accuracy in data processing. Solid dosing flexibility has been addressed through various automated technologies, with Mettler Toledo being the preferred choice for its ability to handle challenging powders. Cross-contamination is managed through robot training, ionizers in balances, and avoiding cleaning of hoppers by dedicating them to single materials.

The implementation of automation faced some cultural resistance initially, but after demonstrating its value and effectiveness, it gained strong support from the organization. Future steps involve exploring more advanced lab orchestration

solutions, further developing machine learning capabilities, and continuing to enhance the digital architecture of the self-driving laboratory.

Automation in R&D Labs

Valerien Segard

The speaker has been working in technical research and development (R&D) at GSK for about a year. They have a background in engineering and have spent a significant portion of the last 15 years in manufacturing, particularly in secondary sites focused on freeze drying and automatic visual inspection.

Technical R&D at GSK involves various activities, including the development and refinement of drug substances and projects. This includes both preclinical R&D and manufacturing processes. The speaker mentions the importance of ensuring ethical practices and the need to transfer analytical research and development methods to different sites within the organization.

The speaker is part of a global team called Project and Digital Sciences, which encompasses several areas. This includes project management, specifically dedicated to vaccines organization, as well as data sciences, such as artificial intelligence (AI) and machine learning (ML), and innovation more generally.

The speaker's current role involves managing a global team responsible for lab automation and robotics at GSK. Their team is involved in defining the strategy and implementing automation solutions in three different R&D sites: vaccines in Belgium, vaccines in Italy, and an unspecified area in the US. The team's vision is to create user-friendly tools and solutions that go beyond standalone projects or tools that remain unused.

The team emphasizes the importance of being user-friendly and continuously improving their solutions. They want to offer integrated and fit-for-purpose solutions that address the challenges faced by the organization. The speaker mentions their preference for two worlds: the world of project management and the world of user-friendly tools.

The speaker outlines three pillars that form the foundation of their team's culture. These are ambition for patients, accountability for impact, and doing the right thing. They believe in leveraging automation, robotics, and other technologies to improve processes, but specifically mention the importance of offering solutions that have a positive impact on patients and adhere to ethical standards.

In terms of their focus within lab automation and robotics, the speaker and their team aim to provide integrated solutions. They want to address global challenges and consider factors like environmental stability in their projects. They mention the

importance of data governance and the touch texture component in any new lab automation projects.

The speaker acknowledges that the provided text contains a lot of information and states that they won't go through all of it to avoid it becoming overwhelming. They refer to the concept of "golden circles" and the importance of clearly defining the team's purpose and organization before delving into specific details.

The speaker's team is focused on developing and implementing lab automation and robotics solutions. They mention being part of the Project and Digital Sciences team, which includes project management for vaccines organization and a group of data scientists specializing in AI, ML, and innovation. They specifically mention managing the global team responsible for lab automation and robotics in GSK's R&D sites in Belgium, Italy, and the US.

The speaker discusses their team's vision, which centers around creating user-friendly tools and solutions that are not limited to being idle or unused. They express a preference for solutions that have a clear purpose and offer value to users. They want to ensure that their solutions align with the organization's culture and values.

The speaker mentions that their team is involved in various projects and initiatives. They highlight the importance of an end-to-end approach, starting from the definition and characterization of needs and ending with success criteria related to change management. They emphasize the integration of data transformation and reporting into experimental design, sample preparation, and analytics, which is not always a common practice.

The speaker provides examples of ongoing projects. One example is the implementation of an end-to-end platform for executing Elisa tests, a common method used in laboratories. This collaboration involves analytical research and development teams and the server quality control (QC) laboratory. The main challenge is orchestrating various platforms and third-party modules for optimal efficiency and tracking equipment usage.

The speaker mentions another project focused on making robot programming in the lab more intuitive. They discuss the development of a web-based application that allows users at GSK to create new methods on robots without requiring programming knowledge. This aims to simplify the programming process and facilitate method transfer between different equipment and suppliers.

The speaker briefly touches upon the application of generative AI in their workflow. While they don't provide specific examples, they express interest in leveraging generative AI for designing scripts and improving processes. They highlight the potential benefits of AI in lab automation and express a desire to explore its capabilities further.

Day 2 Track 1 Automation With AI ML & Robotic Tools In Drug Discovery & Development

How To Innovate And Automate BioTech Workflows

Fausto Artico

The speaker introduces himself, an accomplished individual with multiple PhDs and expertise in mathematics, physics, and computer science. Having worked in Silicon Valley, Orange County, and even at IBM's TJ Watson Research Centre in New York, Fausto's diverse background led him to the world of pharmaceuticals five years ago when he joined GSK, a prominent pharma company in London.

Fausto sets the stage by acknowledging the central theme of the conference: automation. However, he expands on his talk's title, explaining that the principles he will share are universally applicable across various verticals and business units, not just limited to one industry.

He points out the challenges faced in the pharma sector, particularly the difficulty in driving innovation due to legacy systems, fragmented data, and a lack of integration among various processes. Companies often grapple with the problem of trying to leverage emerging technologies while working within rigid, non-adaptable systems that grew through mergers and acquisitions.

Transitioning to his advice, Fausto starts with the idea of automating small activities. He emphasizes that even seemingly insignificant tasks, when automated, can lead to substantial time savings and improved productivity in the long run. This includes automating tasks like data entry, report generation, and routine data analysis.

He then urges the audience to track and log activities diligently. By meticulously recording the time consumed by each task, organizations can pinpoint bottlenecks and inefficiencies in their workflow. Armed with this data-driven approach, they can make informed decisions to optimize processes and allocate resources effectively.

Another key suggestion Fausto offers is breaking down monolithic systems into smaller, more manageable components. Even if the overall time consumption remains the same, dissecting complex processes allows organizations to gain a better understanding of the system and identify specific areas for improvement.

Fausto advocates for a careful consideration of human involvement in the automation process. While some tasks can be fully automated, others may require human intervention or decision-making. Striking the right balance ensures that automation enhances human capabilities rather than replacing them entirely.

Recognizing the industry's skill set challenges, Fausto advises seeking external partners, such as consultancy firms, to gain diverse perspectives and expertise. Collaboration with external partners can lead to valuable gap analyses, strategic evaluations, and assistance in automating specific tasks, propelling the organization forward in their digital transformation journey.

The talk takes an insightful turn as Fausto stresses the significance of maintaining a people-centric approach. While technology, like AI and automation, can revolutionize processes, it is the human workforce that drives success. Companies must prioritize employee motivation, engagement, and skill development. By creating an environment that fosters innovation and embraces change, organizations can ensure a smoother adoption of new technologies and processes.

In conclusion, Fausto leaves the audience inspired and equipped with valuable advice. The pharmaceutical industry's path to successful automation lies not only in technological advancements but also in cultivating a culture that values people and their capabilities. With a united focus on automation, collaboration, and employee empowerment, pharmaceutical companies can embrace change and achieve greater efficiency and competitiveness in a rapidly evolving landscape.

AI/ML In Drug Discovery & Development: Time To Take It To The Next Level

Igor Rudychev

In this talk, the speaker's primary focus is on leveraging artificial intelligence (AI) to drive business and its application in the drug discovery process within a laboratory setting. They express enthusiasm for discussing how AI and machine learning (ML) can be utilized to advance drug research and development.

The talk begins with a reference to a previous presentation on digital twins, which exemplifies how AI is already being utilized effectively in manufacturing and drug discovery. The speaker's main objective is to emphasize the broader impact of AI, particularly in data analysis and processing, which goes beyond the traditional focus on automation and robotics in the lab.

The speaker introduces themselves as a data scientist with extensive experience in applying data science to pharmaceutical research and development over the past three decades. They acknowledge that automation and robotics have been successful in reducing manual and repetitive tasks for scientists, but they believe there is still a gap in automating data analysis and processing.

They argue that the ultimate goal of laboratory work is to analyze data, obtain results, and make discoveries to develop new products. While robotics have significantly reduced manual manipulations, they believe more attention should be

directed toward automating data analysis, processing, and result packaging. To achieve this, they describe how their company has developed a platform to store, process, and analyze all types of data, including real-world data and data generated in the lab.

Before delving into the specifics of AI and automation in the lab, the speaker emphasizes the importance of addressing challenges related to data. They highlight the fragmented nature of data across different platforms and the potential loss of critical data due to personnel turnover or lack of proper data documentation. They propose using AI to simulate missing data and improve data reusability, thus reducing the burden on scientists.

The speaker proceeds to discuss the current state of AI adoption in the lab. They note that while some AI models are used for analysis, many are run manually without a well-defined process or automation. The scientists often run the same AI models repeatedly, which can be time-consuming and limit their ability to focus on creativity and new discoveries.

To address this, the speaker introduces the concept of expert systems, a combination of classical AI and business rules developed by experts. These systems aim to guide scientists through the AI analysis process, allowing them to use AI models effectively even if they are not data scientists. The ultimate goal is to empower researchers, both experienced and new, with advanced AI tools to enhance their productivity and enable better decision-making.

The speaker acknowledges that the drug discovery process is more complex than traditional AI applications, as it involves creating compounds that do not exist in nature. While AI has shown immense success in fields like chess, where it can outperform human intelligence, it is not meant to replace the expertise of experienced scientists in drug discovery.

The talk concludes with the speaker urging the audience to adopt an evolutionary approach to implementing AI in the lab. Starting with simple processes and gradually incorporating more advanced AI-driven automation in data analysis and reporting will enable scientists to focus on creativity and innovation, ultimately driving more effective drug discovery efforts.

Overall, the talk provides valuable insights into the potential of AI in the drug discovery process, emphasizing the need to combine AI technologies with human expertise to achieve optimal results and improve drug development efforts.

Digital Twin: A Tool For Vaccine Process Development And Manufacturing

Sandrine Dessoy

The focus is on the implementation of digital twin technology in the context of vaccine manufacturing processes. The term "digital twin" refers to a virtual replica of a physical process, which is constantly updated with real-time data from its physical counterpart. The digital twin technology enables predictive and prescriptive analysis, allowing for better decision-making, process optimization, and quality improvement.

The speaker mentions three main objectives they had in mind when initiating this project:

1. Ensuring Highest Quality: While achieving consistent quality in biological processes can be challenging due to inherent variability, the digital twin aims to constantly monitor the process parameters and predict their impact on the final product's quality. By analyzing real-time data and comparing it with historical data, the digital twin can help maintain the highest possible product quality.

2. Accelerating Development: The urgency for developing new drugs and vaccines, as evident during the COVID-19 crisis, has highlighted the need for rapid and efficient development processes. By using digital twin technology, scientists and researchers can virtually simulate experiments, optimize process parameters, and predict outcomes, saving time and resources in the physical lab.

3. Promoting the Use of Models: The speaker emphasizes that while mechanistic models have been used by experts in modeling, they wanted to make the technology more accessible and user-friendly for scientists and researchers who might not be experts in modeling. The digital twin serves as a bridge between scientific knowledge and data-driven models, encouraging wider use and understanding of modeling techniques to accelerate the development process.

The application of the digital twin technology in vaccine manufacturing is described, particularly in the context of a bioreactor. A bioreactor is a crucial piece of equipment used to culture cells and produce the antigen, which is the active ingredient in vaccines. The complexity of biological processes in bioreactors makes it challenging for scientists to understand all the reactions happening at once. However, with the digital twin, scientists can create a hybrid model that combines scientific knowledge with machine learning to predict and control the process parameters, thereby optimizing the production process and maintaining product consistency.

Another example provided is the production of an adjuvant, which is a compound that enhances the immune response during vaccination. The digital twin is used to

predict the size of particles during the manufacturing process, which is a critical quality attribute for the adjuvant. By monitoring and controlling the process parameters in real-time, the digital twin can ensure that the final product meets the desired specifications.

The transcript also mentions the platform used for the digital twin, involving data streaming, machine learning models, and the cloud for model refinement. Additionally, it highlights the importance of regulatory approval, as introducing AI and digital twin technology into the core of the process control presents unique challenges that require a stepwise approach and collaboration with regulatory authorities.

Overall, the project showcases the potential of digital twin technology in revolutionizing vaccine manufacturing processes by enabling better quality control, faster development, and improved efficiency while addressing the complexities of biological systems. The successful transfer of the digital twin to commercial operations is expected to further revolutionize vaccine production and delivery.

Overcome Complexity: Does Automation Of Potency Assays Really Have A Benefit

Tanja Gaissmaier

Tanja's presentation titled "Overcome Complexity: Does Automation of Potency Assays Really Have a Benefit" delved into the challenges and advantages of automating potency assays in the pharmaceutical industry.

Tanja introduced herself as a scientist working in the potency SS call center at Building Ingelheim, a pharmaceutical company in South Germany. Her work involves potency assay formats and data strategy associated with various projects. Additionally, she is part of the potency skill center automation team, where she has a keen interest in advancing the automation of potency assays.

The presentation began with an overview of Building Ingelheim, a family-owned pharmaceutical company with a long history dating back to 1885. The company focuses on human health, animal health, and biopharmaceutical contract manufacturing, primarily developing innovative therapies for unmet medical needs.

Tanja then explained what potency assays are—a quantitative measure of biological activity, particularly the ability of therapeutic products like antibodies to elicit specific responses in relevant disease systems. These assays can be cell-based bioessays or cell-free binding assays like surface plasmon resonance (SPR) or enzyme-linked immunosorbent assay (ELISA).

Automation of potency assays offers various benefits, such as time savings, consistent quality with reduced human errors, higher throughput, and lower sample volumes required. However, the challenge lies in the complexity and diversity of potency assays, as each assay setup must be tailored to reflect the specific mode of action of the molecules being tested.

To address these challenges, Tanja's team employs a combination of semi-automation and full automation. They use liquid handling systems like T Confluence and Tekinfluence for sample preparations, serial dilutions, transfers, and reagent additions. Semi-automation allows analysts to perform certain steps manually, while full automation takes care of repetitive and time-consuming tasks.

The presentation highlighted a typical workflow for a simple reporter gene assay using a semi-automated process. Analysts create an input file with plate layout and sample information. The robotic system prepares serial dilutions and transfers them to 96-well plates, while the analyst manually adds cells and ligands. Full automation can further reduce time and increase throughput.

However, the complexity of potency assays presents challenges for automation. Potency assays are not platform methods and often require unique setups for different molecules. The workflows can be time-consuming, and critical reagents may be sensitive to light exposure and temperature changes.

Tanja's team has implemented LabVIEW-based software for essay scheduling, which allows for flexibility in programming variable essay formats without advanced programming skills. They use a Microsoft Access-based essay database to create modular setups for each potency method. Full automation has allowed them to analyze large sample packages and perform DOE (Design of Experiments) for assay development with reduced effort.

Despite the benefits, there are technical limitations. For instance, full automation can lead to longer essay runtimes due to stepwise processing by the robotic system. The team also faces challenges in expectation management, as there might be misconceptions about automation always yielding better precision and speed than manual assays.

In conclusion, automation of potency assays offers substantial benefits, but it requires a case-by-case approach. Semi-automation and full automation can be combined to optimize efficiency and productivity in potency assays, but careful planning and consideration of assay complexity are crucial. Tanja's team continues to explore innovative solutions to overcome challenges and further enhance the automation of potency assays in their pharmaceutical endeavors.