Considerations for Automation of Standardized Methods for Tobacco/Smoke Investigations

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Abstract

Much of Tobacco & Smoke labwork comprises repetitive implementations of standardized methodologies and/or the appropriation of well-defined technologies to novel requirements.

Additionally, regulatory compliance is now an undeniable feature of the Industry and is recognized as being of huge import moving forwards.

Laboratory Automation is therefore key to both challenges; If a task is completed by robotic means, both the actions – and the data trail is viewed by regulators in a different (and usually more positive) light than by equivalent manual methods.

Topics discussed will include the challenges of different Method types typified by examples of extraction/concentration vs 'smoke & report' investigations; How automation can be used to ease ratifcation of the requirements of 21CFR11 and similar rationales; Considerations of approaches to Verification dynamics ; and how to ensure 'Quality data' with associated considerations for long term storage and accessibility.

Introduction

Over the past 25+ years Laboratory Automation has transformed the Pharmaceutical business and some of the lessons learned have been applied to requirements within Tobacco/Smoke Lab analyses.

The more successful documented applications involve quantitation of smoking filter pad contents via automated weighings, the normalization of liquid/liquid extraction methods for same filter pads, and also SPE/SPC concentration methodologies on tobacco extracts to determine trace analytes and clean macro- molecular species from sample types.

The use of both single-arm robotic cells and modular automated workstations (sometimes with a manual/ assistance /override step) have underpinned these efforts toward greater productivity.

Discussion

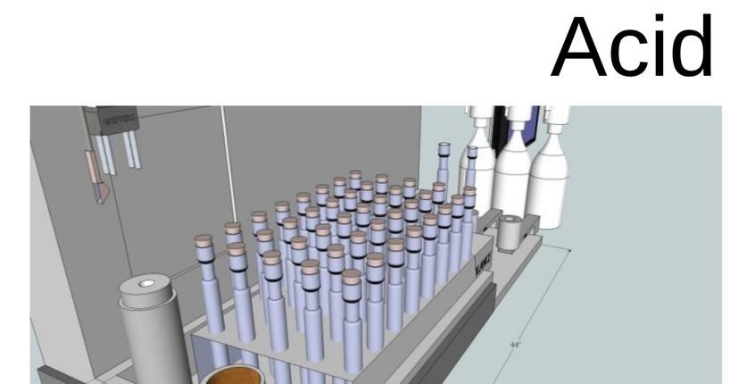
Results prove that effective automation can halve sample throughput cycles as well as double or triple sample number completed over analogous time frames. Significantly the trendline of sample repeats declines by an order of magnitude. [1]

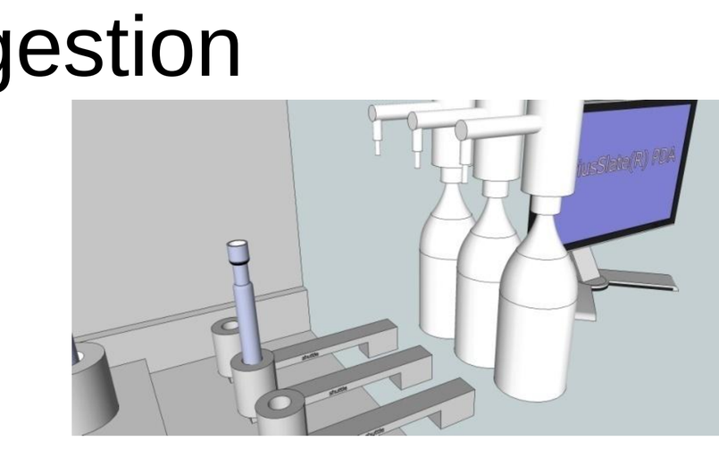
Further, the approach to customization to better fit manual methods is catalyzed by 'building automation in' to processes from their beginnings, Shifting the paradigm of conventional sample processing to an automation compatible equivalent (ie use of homogenates)

Translating/Transference of manual methods to an automated process becomes more facile Personnel utilizing both, see more equivalency between them, hence usage is more readily accepted.
Acceptance and desire to implement successfully is as key to an automation project as it is to any complex project.

Application Examples

Acid Digestion





Results

One of the benchmarks employed for Testing was simple quantification. 2,880 Weighing Tests were accomplished under both Automated & Manual Protocols utilizing exactly the same Analytical Balances and sample materials, inc. barcoded labware.

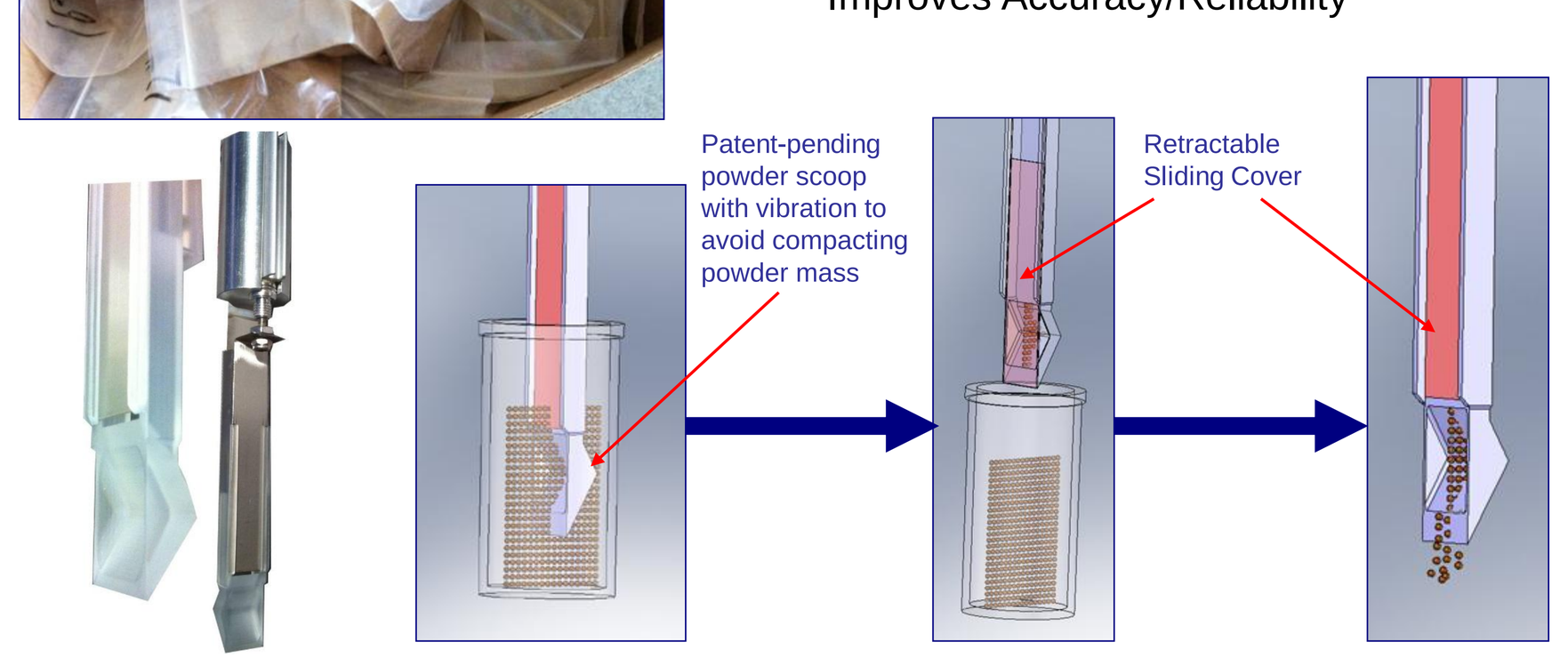
In an effort to minimize bias, a number of University postdocs were required to accomplish 144 Weighings each, using both methods. Total operator time for biobreaks and labnotebook completion is included in Manual Test timing.

RESULTS (20 sets 144 samples each set)	Calculated VARIANCE (STD DEVIATION)^2	Time (mins) to weigh 144 samples (average)	Transcription errors or bad sample ID on results/sample set
MANUAL TEST	3.96×10^{-2}	83.8	1.3
ROBOTIC TEST	4.9×10^{-3}	42.7	0

Sample (re-) Distribution Tools

Automated Tobacco Powder Transfer

Sirius AccuLance® Powder Sampling Relieves the Manual Work of Distributing Tobacco Powder and Improves Accuracy/Reliability



Shredded/Powdered Solids Pipettor:
Stepper-motor driven to provide high precision in sample handling

- Handles a wide variety of tobacco samples
- Ability to address over-dosing
- Replaces tedious manual labor.

Expandable Jaws

Tobacco Sample

Conclusions

One area has grown significantly more important during the past years; the insistence of regulatory bodies that 'if it wasn't documented, it wasn't done' and robotics has the potential to address these concerns head – on.
Increasingly, industries are being asked to provide historical data that they were unaware might be of significance at the time and much time and effort is wasted on datamining or project reworks.
Early adoption, integration and cross validation of automated laboratory systems incorporating quantitative feedback steps (e.g. barcode verification and validated analytical balance/weight data for each successive operation) ensures a searchable 'chain of custody/treatment history' for each & every sample, plus operator ID etc., whether that data is needed today or at some point in future.
This same feature is a strong support plank on GLP/21CFR11 planks, because a validated automated system only requires the addition of an effective & compliance capable Laboratory Data System/Database to provide same. With the ability to ensure data quality by providing discrete security policies for individual entries, Oracle® likely leads the industry at this time.[2, 3]
A secondary data storage is always viewed positively by regulators, and we have observed that PDF copies of concurrently created reports in support of the archived DB data generally provide an ironclad response to even the most enthused of investigators, with optimal tools for searchability.

Bibliography

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2. .Kate, Aniket; Menezes, Bernard; Singh, Ashish (December 2005). "Proceedings of 3rd International Conference on E-Governance, ICEG 2005" (PDF). Lahore: Lahore University of Management Sciences. pp. 156–159.
3. T. J. Kuhn: "Good Practice for the Pharmaceutical Industry from the Quality Assurance Perspective" (tjkuhn.wordpress.com/2008/07/23/'ALCOA – a new standard')