SeerPharma Journal

October 2019

SeerPharma®
CONFIDENCE IN COMPLIANCE

Welcome to the final edition of the SeerPharma Journal for 2019

It's been a busy year with a significant increase in the number of enquiries for assistance from organisations across the APAC region on matters of Quality Assurance and GxP compliance.

In the last Quarter, we attended and sponsored the Malaysian Organisation of Pharmaceutical Industries inaugural Regulatory Compliance conference in Kuala Lumpur, Malaysia. SeerPharma also attended and exhibited at ISPE's South Asia Pharmaceutical Manufacturing conference in Bangalore, India. Both events generated a significant amount of interest for our Online Postgraduate Certificate in GMP with the UTS: Graduate School of Health and regional partnership with market leading software provider MasterControl.

Our partnership with MasterControl grows from strength to strength, securing the largest project for MasterControl ever in the Asia-Pacific region, which we look forward to kicking off in the final Quarter of this year. The software team has been busy working on several existing deployments and are in discussions with over 50 organisations in region on a solution from MasterControl to automate Quality and Manufacturing (EBR) workflows. In this Journal, you'll read an article from MasterControl on how Digitization can help amplify Lean principles in manufacturing.

We were excited to launch a course booklet and video this Quarter, to provide Quality Professionals more information and detail around our Online Postgraduate Certificate in GMP. You'll also read about one of the many requests that we've received to deliver customised on-site GMP training.

In this edition of the Journal, you'll get to learn a little bit more about the types of problems we are asked to address regarding Validating Computer Systems; a common bugbear for pharmaceutical and medical device companies looking to deploy state of the art IT solutions in a GxP environment. Clients turn to SeerPharma to lean on our expertise to bridge the gap between IT and Quality departments.

As part of our initiative to serve our customers better, we've found a potential software solution to assist firms with their Product Quality Reviews (PQRs). In this issue of the Journal, you'll get to learn a little bit more about an off-the-shelf solution that might make your life a little easier.

Being the last Journal for the year, we wish you all the best for the last few months of 2019.

We do hope you enjoy this issue!

2019 ISPE South Asia Pharmaceutical Manufacturing Conference Report

Bangalore, India: 25 - 27 Sep

SeerPharma exhibited and attended the International Society for Pharmaceutical Engineering (ISPE) inaugural South Asia Pharmaceutical Manufacturing conference in Bangalore, India.

The event focused on the product lifecycle approach from drug development to post-market approvals. Topics included critical approaches for successful manufacturing and leveraging quality as a competitive advantage. Speakers included pharmaceutical and biopharmaceutical industry professionals along with regulators from FDA, MHRA, and APAC regions who are subject matter experts in quality and compliance.

With over 30% of all generic medicines destined to USA originating from India, and the highest number of FDA licensed facilities outside of the US, it was an appropriate opportunity for SeerPharma to engage with a number of key decision makers in the generic medicines business.

SeerPharma was inundated with requests for more information on our Online Postgraduate GMP offering with UTS: Graduate School of Health. A significant amount of companies were also interested in our partnership with market leading QMS software solution MasterControl, in particular when they learnt that the FDA use MasterControl internally to help automate quality management processes.

The event was well attended with close to 200 Senior Quality executives from companies like Mylan, SUN PHARMA, Dr. Reddy's Laboratories and Lupin plus senior representatives from the US FDA and MHRA presenting some fascinating sessions on Quality Management, with a focus on hot topics, such as:

- Handling Out of Specifications (OOS)·
- Data Integrity
- Failure to Investigate Quality events

Contact us for more information on SeerPharma's efforts in India

CSV Assistance for Pharmaceutical and Medical Device Companies

Several pharmaceutical and medical device manufacturers in the Asia-Pacific region have approached and engaged SeerPharma for assistance on matters related to Computer System Validation (CSV). Typical requests have seen SeerPharma address computer systems validation approaches to meet the regulatory requirements of Annex 11 of the PIC/S Guide to GMP and US FDA 21 CFR Part 11.

Typical tasks expected of the team have been to:

- Review and update a client's current framework of computer systems validation (CSV) documentation
- Provide assistance on providing content for Policies and Procedures within the CSV framework
- Re-writing the Computer Validation Master Plan.
- Consolidating the inventory list of GxP computerised systems
- Determine a risk priority of each computerised system on the inventory list
- Review and update the IT Infrastructure Qualification Plan
- Develop a remediation plan for addressing systems validation and infrastructure qualification
- CSV on-site mentoring
- Writing individual Infrastructure Platform Qualification Plans as defined in the remediation plan
- Assistance with validation activities and documentation (e.g. requirements, design, test documentation, traceability, reports)

SeerPharma's CSV team is led by our Directors Paul Kerr and Ian Lucas. The team has significant experience navigating the complexities of operating IT infrastructure and applications in regulated environments. With a number of firms deploying various IT solutions (eg: eQMS, LIMS, ERP) that impact product quality, SeerPharma's CSV team is well placed to help bridge the gap between Quality and IT teams that are tasked to implement such systems.

Download Paul's presentation on CSV history and new approaches

Contact us should you wish to learn more about how SeerPharma can assist on Validating IT infrastructure and applications in a GxP environment.

How Digitization Can Help Life Sciences Manufacturers Amplify Lean Principles

1 October, 2019 by Dave Edwards, Executive Vice President, MasterControl

Life sciences manufacturing in 2019 is a dynamic, immensely competitive space in which new markets, ever-changing regulations and exponentially evolving technologies require the C-suite to look for ways to reduce overhead and create greater efficiencies on the shop floor. This imperative means looking for opportunities to improve levels of quality and harnessing new technological tools that will reduce delays and waste, speed up production processes, and help companies achieve greater ROI. The implementation of greater efficiencies and more effective, faster processes on the shop floor translate directly to the continued solvency and profitability of your organization.

Years ago, when I was a manufacturing manager with medical device maker Danaher, I found that adapting to changes on the shop floor is a situational imperative and a critical part of production. There are specific goals executives and managers are trying to hit each year, but the overarching objective is to continuously improve product quality and the experience of the customer.

A key method manufacturing leaders use to keep operations tight is lean, the systematic school of thought for waste minimization in manufacturing processes that doesn't sacrifice productivity. Based largely on the Toyota Production System, lean techniques can help manufacturers achieve gains through the reduction of non-value-added activities and costs.

Lean Manufacturing Principles

Five primary concepts comprise the leading principles typically associated with 1990's "The Machine That Changed the World":

Specify value as perceived by the customer: Not just on the product you provide but the customers' needs and wants.

1. **Identify the value stream:** Rather than thinking in terms of departments, visualize the value stream as an interconnected flow of processes that derive value.
2. **Make the value flow through the value stream:** Prioritize value-adding steps ahead of non-value adding steps.
3. **Pull the value from the value stream:** Avoid inventory management waste by employing a single-piece flow to produce product on demand.ss
4. **Strive for perfection:** The goal isn't to surpass the competition in improvement but continuous improvement in all facets of your organization.

Based on a 2017 case study of Johnson Controls, a global electronic and HVAC component manufacturer, the comparative benefits of implementing lean production measures can be a game-changer. As a result of implementing lean production practices, the company experienced:

- 22 percent reduction in safety affordable incidents;
- 12 percent improvement in quality;
- 68 percent improvement in employee retention;
- A tripling of its energy savings; and
- Exceeded target improvement in year-over-year conversion costs by 700 percent.

A manufacturer can reap significant benefits from lean practices, including waste reduction and increasing value-added production by upgrading equipment, training employees and implementing more efficient processes.

Read the complete article

Learn more about typical workflows MasterControl can automate

A BETTER WAY OF CONDUCTING PQRS

Ian Lucas | Partner and Customer Solutions Business Manager

The requirement to perform regular Product Quality Reviews (PQRs) is mandated in most codes of Good Manufacturing Practice. For most of these, the frequency of these reviews is to be at least annually.

The intent of these reviews is to perform and internal audit on all facets of the manufacturing, storage and use of the products.

Due to the scope of the processes involved (receival, storage, manufacture, testing, non-conformances, deviations, CAPAs, changes, complaints, recalls) as well as the entities involved (sponsors, vendors, materials, personnel, customers, documents), data is required from many sources and systems.

Obviously, the results from the review (if performed correctly), provide either evidence that a product is consistently being manufactured under control or areas that need to be addressed to bring the process back under control.

For this reason, it would be preferable if this review occurred far more often than just yearly. Unfortunately, for most companies, the PQR is a manual, time-consuming exercise extracting data from multiple systems and collating it into a reportable form.

As the format of this data is variable (database, spreadsheets, paper, etc), no single system exists to specifically perform the PQR.

By using a data analytics tool, data can be imported from many sources to a central area, logically connected together and then charted and reporting on as required.

Although not the only option, Microsoft Power BI is gaining traction amongst many companies as a data visualisation tool.

Being a Microsoft product, it has a similar look and feel to Excel and Access.

Although **Figure 1** looks very complex, the task of loading the data is quite simple. The system itself attempts to connect the data automatically based on column names.

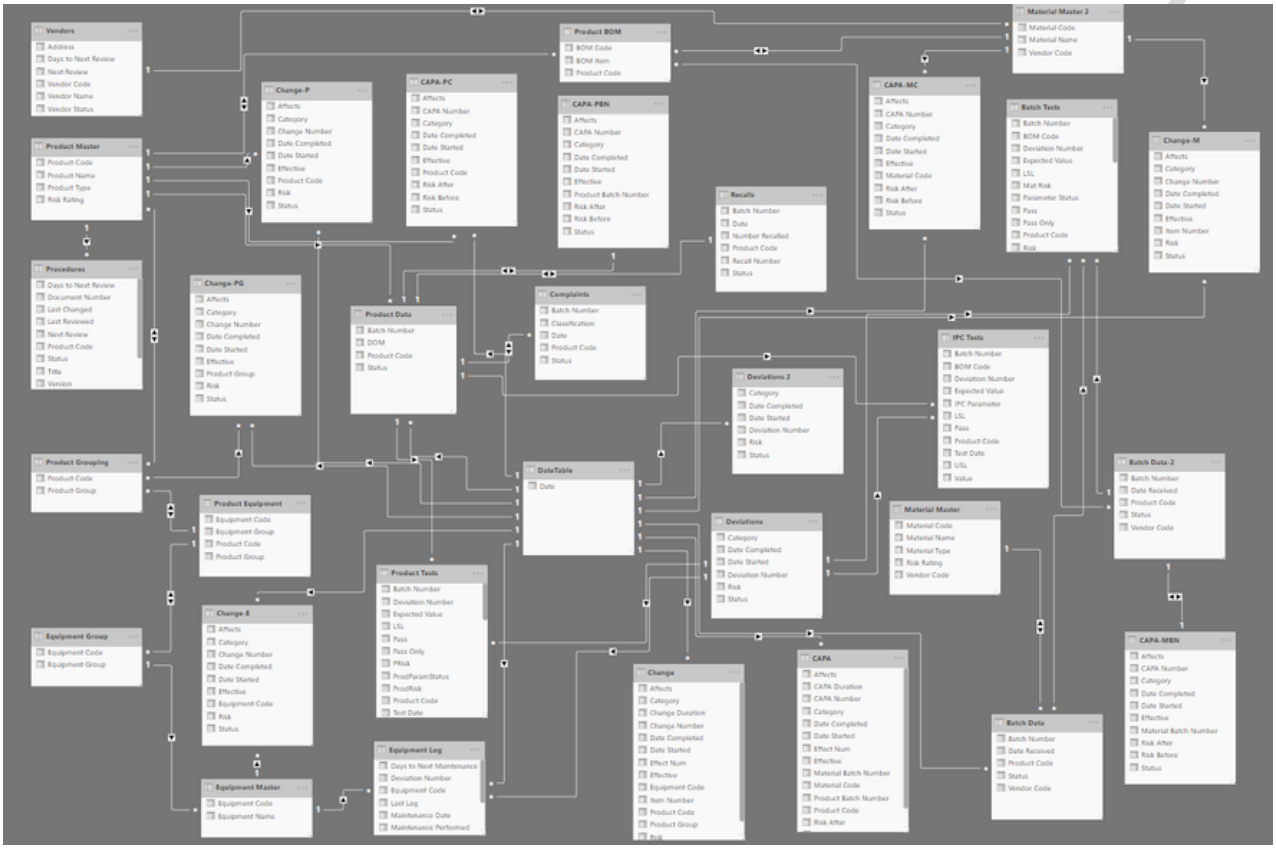

Figure 1 – Data Relationships

Once the data is imported, tables can be split or joined together, additional columns can be added (Figure 2) or data measures (calculations across subsets of data) created.

All original data, new columns and measures can be used in the charting and reporting.

```
1 Mat Risk = IF(ISBLANK('Batch Tests'[Deviation Number]),BLANK(),LOOKUPVALUE('Material Master'[Material Name],
  'Material Master'[Material Code],'Batch Tests'[Product Code])&" - "&LOOKUPVALUE(Deviations[Risk],Deviations
  [Deviation Number],'Batch Tests'[Deviation Number]))
```

USL	Pass	Deviation Number	BOM Code	Pass Only	Parameter Status	Mat Risk	Risk
	Fail	DEV0013	SP0001		Pesticide Residue - Fail	Strawberry Puree - High	High
	Fail	DV190017	SP0001		Pesticide Residue - Fail	Strawberry Puree - High	High
	Fail	DEV0012	SP0001		Pesticide Residue - Fail	Strawberry Puree - High	High
	Fail	DEV0020	MB0001		Storage Temperature - Fail	Minced Beef - Medium	Medium
	Fail	DV190018	MB0001		Storage Temperature - Fail	Minced Beef - High	High

Figure 2 – Additional column 'Mat Risk' created

Once the data is partitioned correctly (i.e. by year, by product group, by product, by starting material, by test parameter, by equipment group, etc), 'visualizations' can be created to display the data.

Figure 3 is an example header page showing yearly summary data for 3 products across 2 years.

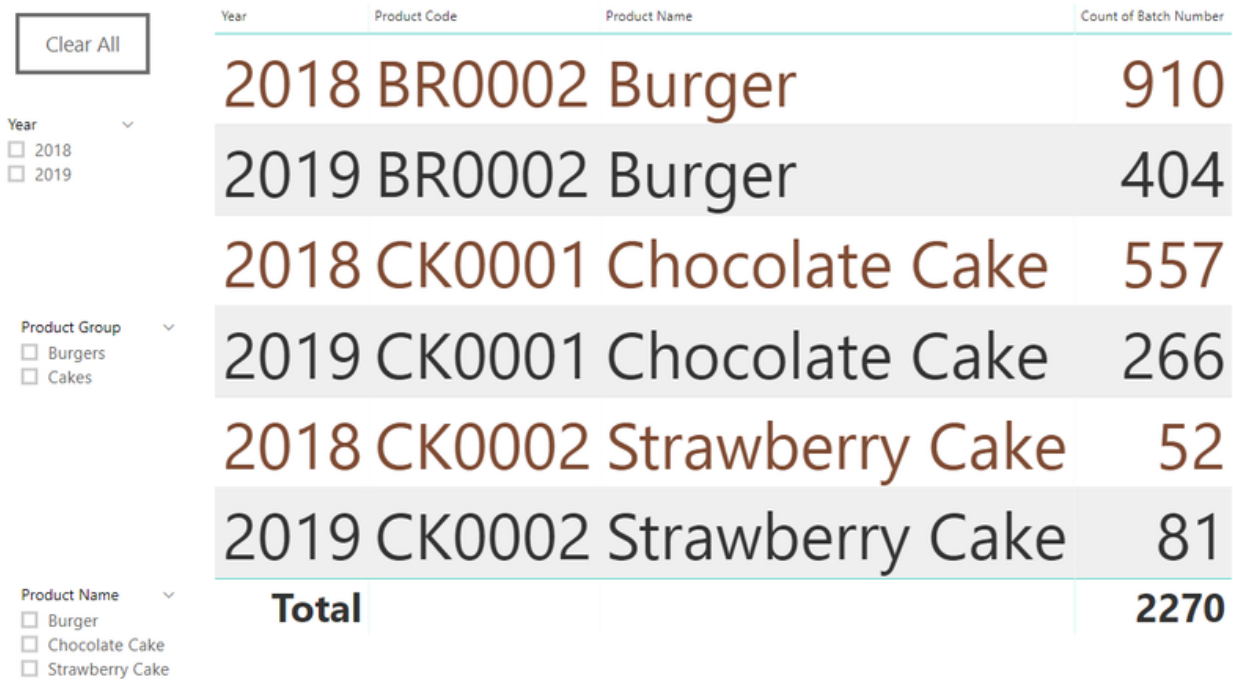

Figure 3 – Report allowing data selection by year, Product Group and/or Product

Data 'slicers' may be applied to the current page report or shared across multiple pages. For example, if '2018' and 'Chocolate Cake' is selected on the header page then only the BOM materials for that (and subsequent raw material status results and deviation risks) are shown on the Starting Materials page (Figure 4).

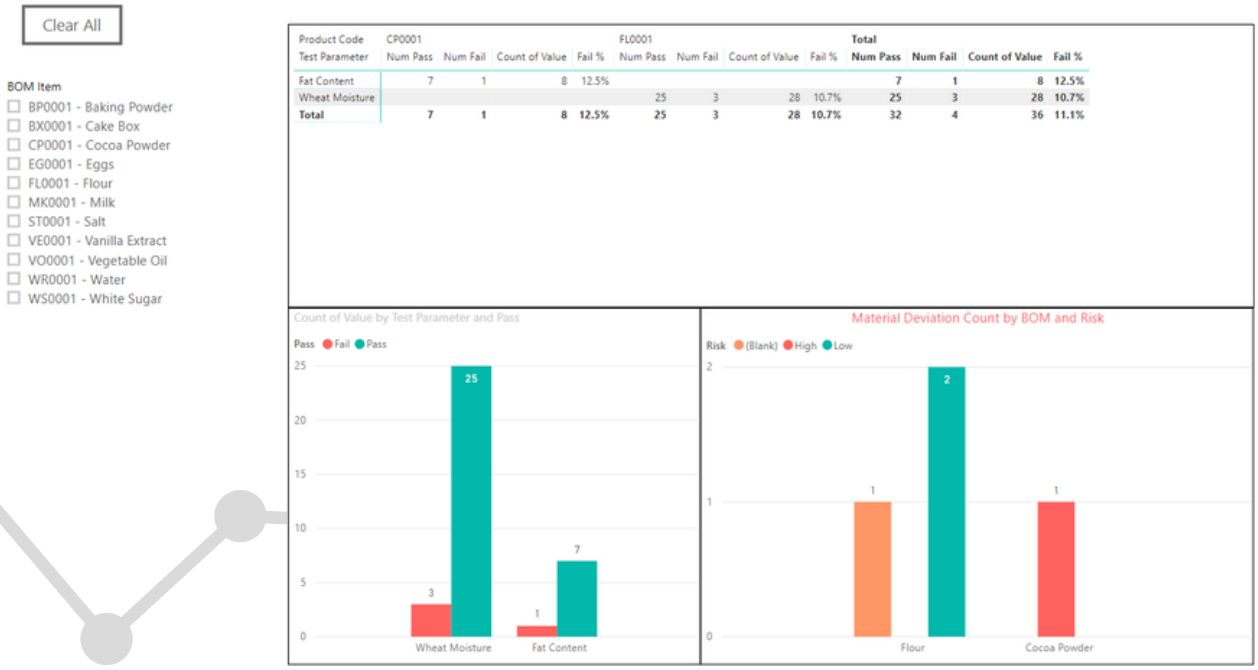

Figure 4 – Restricted starting materials data

Control charts for in-process control tests (Figure 5) as well as finished product results and process capability (CpK) (Figure 6) can be calculated and reported.

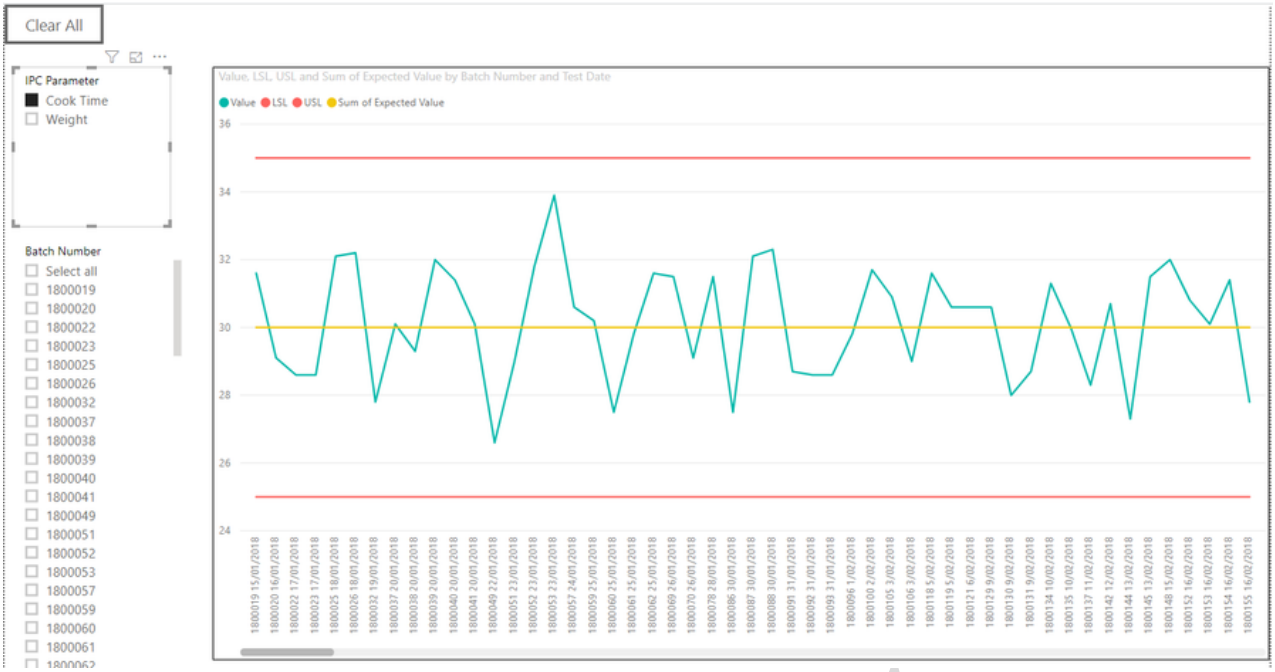

Figure 5 – In-process control testing results

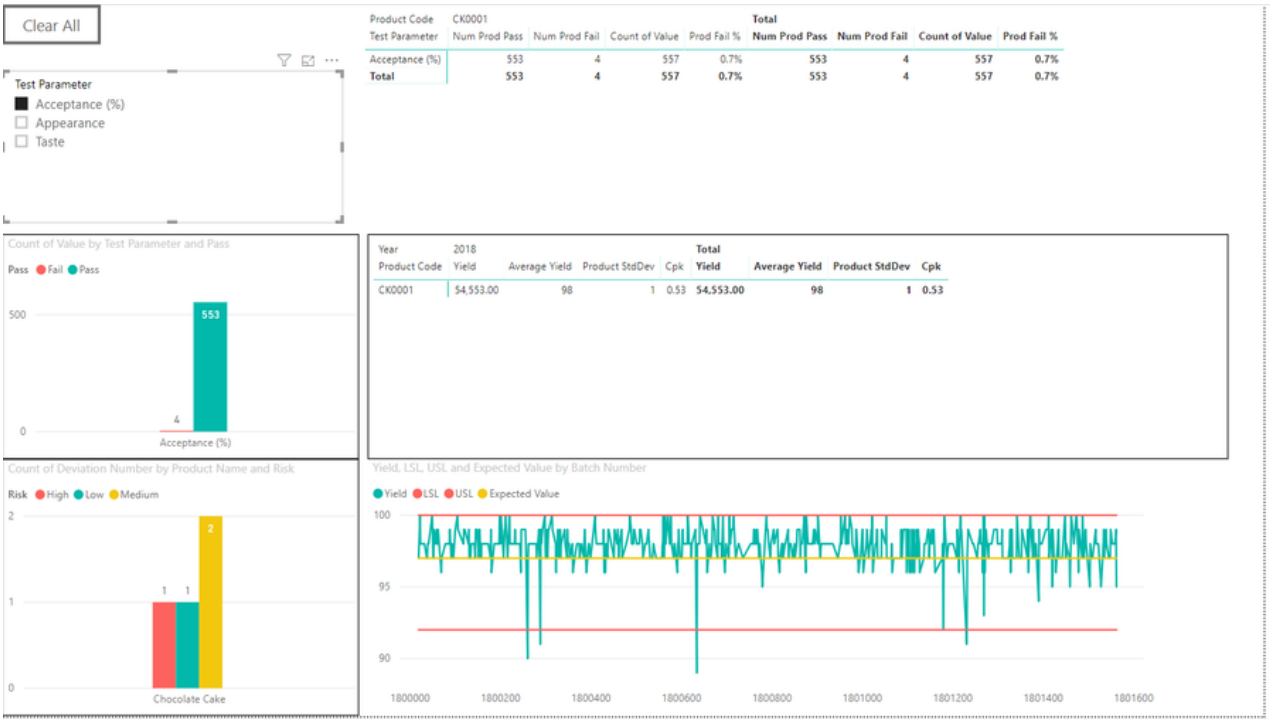

Figure 6 – Finished product results and process capability

Additional report pages can be defined to:

- compare yearly data (on both raw material and products),
- confirm vendor status,
- report on failed batches,
- report on deviation / CAPA / non-conformance data by material and product,
- report on changes by material, product, product group and equipment group,
- report on complaints by complaint category and compare this to resolution category,
- report on recalls,
- report on equipment calibration and maintenance,
- report on relevant documents, labels, agreements and marketing claims

With the output from the reports, a PQR starting report can be created. Justifications, reasonings and PQR wording needs to be added to complete the actual report.

As data can be configured to be auto loaded into Power BI (using a gateway to the source data), or manually updated as required, the data analysis can be performed more frequently than with a manually created PQR. As with other forms of audits, corrective actions and changes can be created as a result of knowledge learnt from the process.

In summary, Microsoft's Power BI can be configured to provide the framework to provide continual review of products and processes.

However, as with any automated system used as part of a GxP process, the solution needs to be carefully planned, and the data structured and loaded in a way that supports the output required.

Contact us if you'd like to learn more about how Microsoft Power BI can help with managing your Product Quality Reviews (PQRs).

SeerPharma at the 2019 Inaugural MOPI Regulatory Compliance Conference

The Malaysian Organisation of Pharmaceutical Industries (MOPI) was incorporated in 1981. The members include manufacturers of pharmaceutical products whose manufacturing facilities are located in Malaysia and are licensed by the Drug Control Authority, Ministry of Health, Malaysia. It was incorporated with a membership of 8 companies and has grown to the current 42; these members are the major pharmaceutical manufacturers of the country. Collectively, the members produce about 35% of the country's medicine requirements.

For over 10 years, SeerPharma, MOPI and the Malaysian National Pharmaceutical Regulatory Agency (NPRA) have worked in unison to deliver technical training modules to the Malaysian Pharmaceutical Industry on international Good Manufacturing Practice (GMP).

SeerPharma was invited to attend MOPI's inaugural 2019 Regulatory Compliance conference in Kuala Lumpur, Malaysia, with over 250 delegates and 70 pharmaceutical manufacturers in attendance. We were thrilled to meet with Quality Director's and Managers from companies such as Pharmaniaga, GSK, CCM Duopharma Biotech Bhd, Novugen Pharma Malaysia, Hovid Bhd and Ain Medicare to name a few.

With a strategic focus to let the Malaysian sector know of our Online Postgraduate Certificate in GMP with the UTS: Graduate School of Health and regional partnership with market-leading software provider MasterControl.

A number of firms in Malaysia are focused on manufacturing Generic Medicines for the markets regulated to WHO GMP standards. However it was clear from the event that there is a stronger focus to work towards exporting more product from Malaysia to PIC/S Member countries. SeerPharma has and continues to assist a number of Malaysian pharmaceutical manufacturers looking to obtain a GMP License from PIC/S Member authorities.

Contact us if you'd like to learn more about SeerPharma's work in Malaysia.

Comprehensive On-Site GMP Training for Pharmaceutical Manufacturer

SeerPharma's training division grows from strength to strength with several companies requesting tailored on-site QA/GMP training for staff. Recently a major multinational pharmaceutical manufacturer approached SeerPharma to address the following key areas of interest for staff at their firm:

- Global regulations
- Good report writing
- Key quality assurance system requirements (including auditing)
- Good Laboratory Practice
- Process validation/design of experiment requirements
- Analytical method validation requirements
- Biological assay validation & control requirements
- Data Integrity

In response SeerPharma tailored a 4-day training package for the firm addressing these needs, and customising our content to work with the clients existing business practices.

Day 1

The Regulated Environment (2 hours)

- List the major GMP regulatory bodies worldwide (briefly)
- State the difference between Regulations, Guides & Codes (briefly)
- Assess the current status of International MRAs and MOUs (briefly)
- Describe how governments regulate products and manufacturers in relation to the client's' business
- State the essential requirements for GMP compliance in relation to the client's business

Good Report Writing (1.5 hours)

- Good writing practices and translating this into effective report writing
- Why effective report writing is important

Key Quality Assurance System Requirements (3.5 hours)

- What is a Pharmaceutical Quality System?
- Quality Risk Management
- Key Quality System Elements for Continuous Improvement·
  - Failure Investigation and Deviation Management
  - Change Control
  - Product Quality Reviews (PQRs)
  - The importance of auditing (internal and suppliers)

Day 2

Good Laboratory Practice requirements (3 hours)

- The key elements and basic principles that make up GLPs and GMP in a testing laboratory and production environment
- The importance of records, raw data, traceability and documents to Quality Systems
- Your role and responsibilities regarding GLP and GMP compliance

Process Validation/Design of Experiment requirements (4 hours)

- Requirements for demonstrating that specific products and processes consistently meet predetermined specifications
- The current approach of PIC/S GMP Annex 15
- The life-cycle approach
- A roadmap for process validation
- Tools and templates for process validation
- Design of Experiments (DoE)

Day 3

Analytical Method Validation requirements (4 hours)

- Performance parameters required for analytical method validation
- Acceptance criteria for analytical method performance parameters
- Requirements for inter-laboratory method transfer
- Calculating the capability of a test method

Biological Assay Validation & Control requirements (3 hours)

- Identify biological assay method validation criteria
- Prepare a validation plan for a microbial limits test method
- Viral applications

Day 4 (half day)

Data Integrity (3.5 hours)

- Integration of DI into your QMS using a risk-based approach
- Protection and security of raw data and original records
- Control of your data when utilising vendor third parties
- Developing practical audit and remediation strategies for DI

With a bank of content that has been developed and over 30 years, SeerPharma is well-placed to tailor and deliver QA/GMP training sessions to your staff on-site.

For more information on our most commonly requested courses to run on-site, please visit: https://www.seerpharma.com/services/qa-and-gmp-training/on-site

Contact us to learn how we might be able to assist with your internal training needs.

LEARN MORE ABOUT OBTAINING A POSTGRADUATE QUALIFICATION IN GMP

SeerPharma has partnered with the University of Technology Sydney (UTS) to design and deliver postgraduate qualifications in Good Manufacturing Practice (GMP).

The Graduate Certificate is already available online and we are on track to bring the Graduate Diploma in GMP online by February 2020.

To help with providing more information about this program, we've put together a Course Booklet to download and share amongst your network.

Download Course Booklet

We have also produced a video to showcase the learning experience of obtaining a postgraduate qualification online.

Watch The Video

We're excited to have registered and received interest from both individuals and companies looking to roll out these GMP qualifications internally to assist with their professional development programs.

The course at UTS grows from strength to strength; below is a picture of the latest cohort of first year students to enrol both on-site and online.

Contact us if you'd like to learn more about this unique University program designed by industry, for industry.

You can also visit our website for more information:

https://www.seerpharma.com/services/qa-and-gmp-training/postgraduate-gmp-training/online-graduate-certificate-in-gmp

Meet Online Student Esther Kopp

"I chose to study this course online as UTS is the only university that offered tertiary studies in GMP, and I am living in a different state.

Automating Quality and Manufacturing Records with MasterControl

Since announcing our partnership with MasterControl, SeerPharma has been inundated with requests for information and personalised demonstrations of this market leading software solution.

MasterControl's suite of solutions to automate workflows andprocesses in Quality and Manufacturing operations are proving to be quitepopular. To help address this interest, SeerPharma has published an overview (with embedded videos) of the most commonly requested modules.

See the Modules

MasterControl recently launched its Manufacturing (Mx) solution which creates and manages Electronic Batch Records (EBRs). The solution natively integrates with their existing Quality (Qx) solution and is winning over customers in the US and Europe. SeerPharma is in discussions with several APAC clients to deploy the EBR solution into their operations.

Watch an Overview of the EBR Solution

Helping companies move from paper to a paperless solution in Quality and Manufacturing will ensure greater:

- Transparency across your organisation
- Efficiencies in managing Quality and Manufacturing events
- Ability to understand your state of control over your operations
- Readiness for Regulatory, External and/or Internal Audits

Contact us if you'd like to learn more about a solution from MasterControl.

SeerPharma & MasterControl at AusBiotech 2019

SeerPharma Partner and Software Products and Services Manager, Rohan Bhatia, will be joining MasterControl at Booth 418 during the AusBiotech 2019 event.

If you're attending, please come and say hello and learn more about the Manufacturing (Mx) solution with Electronic Batch records (EBS) and Quality (Qx) solution with modular electronic Quality Management Systems (QMS).

Learn More About AusBiotech 2019

Upcoming Training and Events

Training Course	Date	Location
Good Aseptic Practices for Compounding Pharmacies	28-30 Oct.	Melbourne
Product Quality Reviews (PQRs)	28 Nov.	Auckland
Validation - Get it Right First Time	November	Australia and New Zealand
GMP - What You Need to Know	December	Australia and New Zealand

Event	Date	Location
AusBiotech 2019 (SeerPharma attending with MasterControl)	30 Oct. to 01 Nov.	Melbourne

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