Review Article

Overview on Softwares Used in Pharma Industry

Sanika R. Joshi*, Vijay R. Salunkhe
Department of Pharmaceutical Quality Assurance, Rajarambapu College of Pharmacy, Kasegaon - 415409, Maharashtra, India.
***Corresponding author's E-mail:** sanikajoshi30@gmail.com

Received: 08-01-2020; **Revised:** 15-02-2020; **Accepted:** 24-04-2020.

ABSTRACT

The whole pharmaceutical areas needed various innovative and scientific solutions to solve the current problems related to cGMP practices, production, documentation, regulatory body requirements (eg. US FDA, WHO, EU-GMP, PICS), quality of product etc. to overcome such problems different computer system software plays important role by monitoring and maintaining the current practices of pharma industry. By installing such software will help pharma industry to improve their cGMP practices and fulfillment of regulatory body's requirements. This article gives overview on different types of software used in pharmaceutical industry. It also covers importance and their need in pharma industry. It also covers the meaning of software used in pharmaceutical industry.

Keywords: Computer system software, cGMP practices, regulatory body's requirements, quality of product, etc.

INTRODUCTION

Every industry's lifeblood is creativity, the discovery and development of new drugs is carried out with unique challenges, ethical implications and social responsibilities as well as the method seem arcane.[1]

Nowadays, it is only possible to understand the complex processes and effectively and efficiently handle resources, money and manpower due to computer software in the pharmaceutical sciences area. Computer software may help relieve medical professionals from daily documentation and other clerical duties, reduce errors and increase accuracy in data transmission and storage, and reduce the use of animals and chemicals, improve productivity and provide solutions for moment-consuming manual tasks, develop uniform standards and continue monitoring or transactions, and fast and direct access via remotely located terminals to the different information.[2]

Aside from the fact that nearly 20 years already have ratified since the introduction by the FDA of key electronic validation safety standards, the health care industry is still struggling to comply with compliance regulations and adapt to new technology while continuing to deliver products in a secure and timely way.[3]

In the Era of the internet, where software is more mission-critical than ever, it's no longer enough to excel some of the time for your development projects. You need to consistently deliver excellent software efficiency, and do it faster than ever.[4]

Historically the pharmaceutical and biopharmaceutical sectors have not been the precursor of revolutionary engineering solutions and modern chemical engineering concepts. The manufacture of drug products has been monitored for many decades through a regulatory framework which safeguarded the quality of the final product and checked the characteristic of batch-based operations, raw materials and end products fixed process conditions, and in-process materials. Limitations related to this consistency have been widely recognized by testing thinking for both small molecule and biopharmaceutical goods. Many fields of production and related industrial sciences, one on either hand, have successfully implemented advanced techniques to enhance our current understanding of processes and goods. Throughout the first few decades, even so, there has also been growing concern in increasing drug safety and quality it while at the simultaneously reducing pharmaceutical production costs by introducing more organized pharmaceutical development and production strategies.[5]

There are various definitions for the term computer system. European concept of an informatics system and program.

Computerized System

A system including the input of data, electronic processing and the output of information to be used either for reporting or automatic control.

System

Is used in the sense of a regulated pattern of interacting activities and techniques which are united to form organized wholes.[6]

Regulatory Requirement for Computerized System Validation

The FDA study of 3140 medical device recalls conducted in 1992 and 1998 shows that 242 of them faced deficiencies in the program. Such recalls related to software, 192 were caused by software bugs made after the program received and implemented improvements. System testing and other associated good quality software engineering activities mentioned in this to prevent these vulnerabilities and consequent recalls. Computer validation is a

requirement for quality control of the system, which was released in the Federal Register on 7 October 1996 and came into effect on 1 June 1997. Software validation is worn as a tool in medical devices and has been used to render the quality system product.

Pharmaceutical Manufacturing Softwares

Three of the most critical features companies are looking for in their pharmaceutical manufacturer's software are:

Inventory management

Because pharmaceutical ingredients and goods are often controlled substances and must be guarded, the value of a comprehensive distribution system to track such controlled substances can be imagined. Substances used in the process have very frequently short shelf life as well. They must be rotated and used in a timely manner.

Production management/quality assurance

Control of production must include scaling of the receipts for various batch sizes. The batch monitoring is required as part of the recall control, again for both ingredients and products.

Regulatory compliance

A ton of pharmaceutical manufacturers have to wade through the compliance with the regulations. The shipment not only needs to be documented, but it must be secure, recorded and not polluting to disposal. Only start-up production is regulated for some compounds. The FDA Process Analytical Technology (PAT) program will help in the development of new and improved pharmaceutical production systems.[7, 8]

For pharmaceutical manufacturers software should examine the following functions while considering their unique requirements

Table 1: Requirements of softwares for respected working area

Working area	Requirements
Formulation and batch sizing	The program should include control of the formulations, including replacement of ingredients and batch scaling. Advanced systems can match batches to product quantities in stock. The system should provide formulae of various strengths.
Available to promise, capable to promise	Available to promise (ATP) and capable to promise (CTP) are measures of manufacturing capacity. The system should calculate the ATP and CTP for any stock item, accounting for ingredients on hand and any work in process.
Lot tracing and recall management	Every lot has to be monitored and identified. That lot's ingredients also need to be tied to their individual batch number.
Recall management	There are two explanations for implementing the recalls. Firstly, a process error allows a product to become tainted or polluted. Second, an ingredient is either infected or tainted. In either case, all affected batches must be reported by the system and the customers who purchased those batches must.
Hazard Analysis Critical Control Points (HACCP) compliance	In accordance with HACCP Principle 7, the system should support reporting for Hazard Analysis Critical Control Points (HACCP): "Establish record-keeping and documentation procedures."
FDA compliance	The FDA has the authority to regulate traditional and homeopathic pharmaceuticals; the labeling requirements are identical but have unique variations. Where applicable, the program should mark normal and homeopathic items correctly.
Drug Enforcement Agency (DEA) compliance	If the pharmaceutical company makes drugs or uses ingredients monitored by the Controlled Substances Act, this is subject to DEA supervision. The program will record compliance with the act and have access to an existing database of prescription drugs, approved chemicals and the like.
Environmental Protection Agency (EPA) compliance	The drug can be regulated by the EPA if the pharmaceutical manufacturer makes or uses products listed under the Toxic Drug Control Act. The company must maintain all compliant documentation and prepare a pre-manufacturing notice before creating a new product.
Quality assurance	The framework will endorse checking for quality assurance (QA). The protocols should be documented through the system, and implemented. The QA system will classify samples randomly for testing and equate test results with expectations. Advanced systems will feature dashboards which alert administrators to quality issues.
Process analytical technology support	The system should identify critical process parameters as part of quality assurance testing, and define their impact on critical quality attributes.
Code of Federal Regulations 21 Part 11 compliance	Strictly speaking, since the law stipulates administrative and operational controls as well as technical implementation for electronic and hybrid record keeping, no software package can be 21 CFR Part 11 compliant. Nevertheless, by

Working area	Requirements
	applying the technical requirements in full it can help 21 CFR Part 11.
Current Good Manufacturing Practice (cGMP) compliance	Compliance with cGMP is required for many state and federal regulatory agencies, as well as for insurance purposes. The software will produce compliance reports which are needed.
Yield variances	For each batch the system will track actual yield versus expected yield. The program would monitor significant variance based on user-defined thresholds and indicate if there are such large variances that it should notify regulatory agencies.
Packing & drumming	The distribution system expects to be able to measure and price items in different sizes of containers. Also, it must define or produce correct container labels.
Inventory storage planning	Many pharmaceuticals need a special environment for storage. The procurement and receiving processes should inform staff of any particular requirements.
Expiration tracking	There may be minimal shelf life for both pharmaceutical ingredients and pharmaceutical products. The company has to track the inventory that has expired and is close to the end of life.
Shipping	Many pharmaceutical products have shipping restrictions either via USPS or common carrier. In some cases, the contents of a package may not appear on external labelling. The system should identify any specific requirements and produce suitable labels for shipping.

Different types of software used in pharmaceutical industry [7, 8, 9, 10].

1. ProcessPro

ProcessPro offers a comprehensive ERP system with complete production, stock and economic integration–a total system from the start of order entry to production and accounting. The program addresses the essential batch processing needs involving on and reverse lot quality control and sophisticated procedures and ingredients management. The better integrated quality control functions remove of a need to re-enter data, and the centralized database offers instant and reliable revenue, production, and inventory visibility in the company.

The Power and Backing of Microsof

ProcessPro's ERP systems are specifically developed on Microsoft's leading edge technology —.NET, SOA and SQL Server — and specifically designed for adaptability to accommodate the unique needs of your specific business while keeping up to date with the latest standard update. Development, Stock, Performance, Financials and Sales are complemented by Warehouse Management, Enforcement, Point of Sale, Direct Store Supply, Maintenance and Repair, Field Service, Fixed Assets, Project Costing, Payroll, Human Resources, EDI and much more. The critical business needs of process users are integrated into the software solution.

2. ProcessPro's Comprehensive Analytics and Reporting Software

The app ProcessPro offers dynamic views' on - the-fly' with limitless reporting opportunities. Users are able to record, scan, filter and query as appropriate, gaining easy access to the data and manipulating and visualizing the information. Pre determined and customizable dashboards offer key business details, enhancing out - of-the-box management capabilities. It is an advanced analytical tool; featuring a robust data reporting warehouse, Advanced Analytics enables interactive visualization, reporting and analysis of your data from any device (desktop or mobile) anywhere in your business. In any case, graphing, sorting and digging into your critical business details, combined with detailed pre-constructed reports, metrics and KPIs, scheduling and warnings provide an essential tool for your business analysis. Predefined links and the data organization also provide the ability to extend the study to other pre-constructed business resources.

3. BatchMaster ERP

BatchMaster Software focuses 100 per cent on designing and providing software solutions for the food, chemical, nutraceutical and pharmaceutical industries. It is a formula based, process manufacturing application that supports R&D, formulation, packaging, costing, production, QC, QA, inventory, compliance, and traceability. Sample management, preparation (MRP), scheduling (MPS), warehousing, alarm management, and sharing of EDIs are optional modules. Such technologies allow businesses to streamline and grow their operations rapidly, cut costs and easily comply with today's increasingly stringent regulatory mandates.

4. S2K Enterprise Software

VAI's technology roadmap, [VAI's] mutual strategy with IBM, offers businesses with a business that relies on best practices in the industry that exploits technology to develop quality and boost performance. The S2 K product family includes distribution, manufacturing, retail, utility, and leasing solutions; with industry-specific features for Durable Goods, Apparel, and Pharmaceutical companies.

5. S2K Analytics

VAI S2 K Analytics is a robust Business Intelligence platform that would help you manage efficiency, have a clear idea of sales and productivity, track cost and properly manage distributed and dynamic suppliers. This simple to use yet

useful tool links the workers with knowledge from S2 K Enterprise so they can make better decisions.

6. Mar-Kov Chemical Management System

Mar-Kov software focuses on producers based on Process, Batch, and Recipe / Formulation. It may be appropriate for- Chemicals, Pharmaceuticals, Cosmetics, Color and Fragrance, Paints and Coatings, Food and Beverage, etc. It provides strong traceability for producers, loosening the burden of meeting FDA, HACCP and other regulatory requirements. This replaces your batch paper records with an automated batch electronic recording system. It increases efficiency with barcode monitoring at the wireless warehousing and container stage. This software is a fully featured, integrated LIMS framework with MES and Inventory Management. The bar-coding is used to ensure accuracy throughout.

7. ResponsePro

2 M Technologies, Inc's ResponsePro is an ERP (Enterprise Resource Planning) system for the pharmaceutical, medicinal, food, and chemical industries. Since 1987 2 M has helped businesses get the most out of their investment in technology. ResponsePro is available in either Linux or Windows environments and offers you a competitive advantage to increase productivity and profitability. Publishing reports to safe websites, Powerful lookup capability for any inquiry or entry screen for faster action / entry, it has functionality.

8. MAXLife365

MAXLife365 addresses Life Sciences companies ' industry-specific needs producing FDA regulated products. MAXLife365 is an end-to-end approach addressing the biggest challenge facing a Life Sciences company: quality control. This increases your visibility in product efficiency, leading to better decisions and higher revenues and benefits. This allows quality control and quality assurance systems to work with each other as part of the business system, and to be transparently available for review and reporting. MAXLife enables you to monitor product quality, proactively see and adapt to manufacturing uncertainty, meet GMPs, Sarbanes Oxley and 21 CFR Part 11 and Part 820 standards, and simplify computer system validation.

9. Shark ERP

For manufacturing companies, Shark ERP is a creative & fully integrated ERP solution. It is designed especially for organizations in the chemical, paint & pharmaceutical industries. It provides dual mode (online / offline) hybrid deployment that addresses regular connection and bandwidth problems so that users can continue to operate transparently as if they were in online.

10. Ceecom Manufacturing – ERP

The Ceecom ERP System consists of a series of integrated modules which can be designed and tailored to suit your needs. Such modules make up the core database that drives all aspects of a fabrication system. Our ERP platform provides you with on-line multi-user transaction processing, providing accurate and immediate information across the enterprise. The Ceecom ERP program is developed to satisfy the Apparel and Footwear, Electrical and Digital, Food and Beverage, Industrial Products, Pharmaceutical and Biotechnology Industries specifications.

11. O2 Process Manufacturing

O2 Process Manufacturing ERP software was developed for process manufacturers by process fabrication experts. It is a complete system from consumer requirements and formula engineering / costing to manufacturing, quality control, regulatory monitoring and protection for managing the entire business life cycle. EVS offers ERP systems for industrial bakeries, food and beverage production, nutraceutical manufacturing, manufacturing of health and beauty products, chemical manufacturing, paint manufacturing, pharmaceutical and life sciences sectors.

12. SYSPRO

SYSPRO is an enterprise resource planning (ERP) solution developed for manufacturers and retailers to simplify the business complexity. SYSPRO can be installed in the database, on the premise or via a premium model and can be accessible from any system, anywhere, anywhere. SYSPRO provides a comprehensive, fully integrated business system covering payroll and financial management, inventory management, order management, planning and scheduling, supply chain management, warehouse management, production management, customer relationship management (CRM) and business intelligence management.

13. Document Flow Manager (DFM)

Automatic processing of documents as they arrive electronically. Open architecture allows easy linking/integration to other applications, receive and transmit transactions using e-mail. Translate XML documents using an XSLT translator. Transform documents from one format to another using the DFM or product such as BizTalk. Transactions tracked and processed through Microsoft Messaging Services.

14. Engineering Change Control (ECC)

User-defined workflow replaces traditional paper trail that accompanies product design changes, electronic visibility of each step of process, electronic notification of new tasks with automatic reminders, electronic sign-offs. On-line or batch archiving of old revisions/releases in XML format, Prevents changes to ECC-controlled BOM without an ECO being raised. It contains Security access control at each step of the process.

15. F9

Create virtually any financial report that a company requires for in-depth business analyses Hotlink the SYSPRO

General Ledger data to Microsoft Excel, Lotus 1-2-3 for Windows or QuattroPro via Dynamic Data Exchange (DDE), Smart templates, Performs what-if analyses, Simultaneously accesses information from multiple companies.

16. Factory Documentation

It Provides part material requisitions. Provides manufacturing workers with estimated launch and termination dates for each project within a job sets the approximate length of each operation Provides routing guidance to production personnel. Accesses to an audit trail of released products and completed activities including quality control. This helps to educate manufacturing workers about the next operation to be conducted. This defines 4 different formats for different uses of factory documents, such as: work tickets, material requisitions, route cards, and passengers. This includes the printing of bar code on documents for use with automated data collection systems.

17. Forecast Pro

Forecasting tools that benefit planning, cut inventory costs and serve to decrease stockouts, graphing and report generation to illustrate forecasts, historic data, confidence limits and safety stocks, standardized set of diagnostic screens that help to compare and evaluate models, graphs residuals and error autocorrelation as well as key numeric statistics. Gives results in clear, understandable business terms, eliminating the need for specialized training or a background in statistics. Forecasts can optionally be used to update MRP forecasts

18. General Ledger

It gives graphical views of actual performance or budgets for quarters and prior years, retains unlimited detail and summary histories. And can handle unlimited number of accounts; have ability to drills down into the sub-ledger to find the source of ledger details, including offsetting entries. It provides the ability to support European Monetary Unit (EMU) and FASB 52 requirements, maintains currency exchange rate history, allows redefinition of financial year, maintains up to 10 budgets for each ledger code, produces consolidated financials for multiple companies, and defines ledger code groupings. It provides password protection for sensitive accounts. Its Multi-period accounting allows 2 years of open periods, contains ability to imports budgets and journal entries from third party products such as payroll. Built in Financial Report Writer, with XML support, allows unlimited user-defined statements. Full audit trails are added to General Ledger for all transactions

19. Graphical Job Schedule

It presents a graphical view of the utilization of each work center by job and day. Monitor each job and identify potential problem areas before they become obstacles, View Available to Promise (ATP) graphically, highlights overloads as well as under loads. The effect of queue time, elapsed time, move time and routing on dates and capacity loadings is apparent, user can review routing procedures and monitor it. Work Center Capacity Calendar is visible in its entirety and can be easily manipulated. Permits complete reload of each job on a forward or backward basis Demand pegging and supply chain operation available at a glance with the ability to update shipping or due dates View and control multiple constraints in the production schedule.

20. Interface System and Business-to-Business Trading

Allows the installation of only the required modules on individual sites, specifies which transactions will be exported to each site, allows users to decide when and how frequently different locations will be updated, manages remote branches without duplicating data entry, makes it possible to choose whether to transfer all information with each update or to update transfer only the changes which have occurred since the last update, uses pre-defined ASCII format files or exports XML documents to easily communicate with customers and supplier, Imports customer sales orders Exports order acknowledgments and delivery notes. Gives a complete log of all transactions, gives a detailed status report and transmission log for all sites, each interface file is assigned a sequential log.

21. Lot Tracking

ORION Enterprise For Process Manufacturing, you can customize how you wish to track ingredients and products to better meet your business and customer requirements. This facilitates monitoring in ways that your company and your clients are relevant and anticipated to see. Characteristics of a lot identified by consumerIt gives detailed visibility across the supply chain beginning with vendor materials and into the destination of the customer. Allows easier method design and construction by point 'n' click ingredient selection, mentioned replacement if required, and context assignment.

22. E-Z-MRP

E-Z-MRP is an integrated production system that encompasses all the functions you need to control your production operations. E-Z-MRP "is designed for small-scale manufacturers–from start-up to $20 million. It works just as well in job shops or in order-building environments as in stock-building or predictive operations. E-Z-MRP" has been successfully implemented in a remarkable variety of small manufacturing companies – medical instrumentation, appliances, automotive, pharmaceutical, furniture, spraying systems, orthodontics, firearms, as well as finding use as an instructional aid in universities. E-Z-MRP "runs on any Windows-based PC-either specific user or server.

23. Tropos

Solarsoft provides producers, retailers and wholesalers throughout North America, Europe and Asia with innovative enterprise software and IT services. Tropos was

designed for demand-driven short-cycle manufacturing and the needs of regulated industries. Most ERP products were designed around discrete fabrication. It was, by comparison, planned from the beginning for process manufacturing. This combines Recipe-based Materials Requirements Planning (MRP) and MRPII. It is ideal for food processors and packers, pharmaceuticals, mill and metal processing, specialty chemicals, and general manufacturing in process-oriented industries, especially those that supply the major retailers or those that distribute short-lived products.

24. EDI

The speedy and efficient data transfer amongst supply chain partners is of paramount importance in the fast moving environments experienced by many enterprises. , EDI messages can be received and processed automatically, with outgoing messages being generated in response to certain events. In this way, sales orders can be received, validated and recorded without human intervention, with any validation errors or discrepancies being highlighted for review. The selling orders issued are the same in nature as those submitted by hand, ensuring a smooth handling of orders. EDI messages covering invoice and advance shipping notice information may also be automatically generated on dispatch.

25. SapphireOne

SapphireOne is On-premise Mac and Windows operating system software suite. The software covers ERP, CRM, DMS and accounting for companies. There is also an optional web kit, which gives users access to the software from any computer with an Internet connection. It can handle organizations of almost any scale. The platform makes it easy within a single system to handle multi-company companies. Companies working abroad are also funded by multiple currencies.

26. NetSuite

NetSuite Manufacturing Edition Provides integrated inventory management, stock management, accounting and financial planning, order management, customer relationship management (CRM), and e-commerce platform. Offered as a cloud-based solution and distributed on the internet, NetSuite can be used by manufacturing companies to control production orders, to restore basic inventory levels and to ensure the success and quality of special products. The program also supports inventory for multiple locations, assembly management specifications, materials billing, work order management, complex calculation systems, barcoding procedures, and other required business processes in the manufacturing sector. It may also be able to integrate delivery processes with existing carriers like FedEx.

27. MasterControl Quality Management System (QMS)

MasterControl Quality Excellence (a QMS Software Solution) is an integrated quality management system that eliminates the need to paper-based quality processes. It helps life-science companies adhere more efficiently to the ever-changing FDA and ISO quality standards. It also helps you automate all database-based systems for program application, timetabling, read-up, monitoring, escalation, review, and approval. The key framework in the MasterControl suite combines all quality processes including control of improvements, feedback from consumers, corrective / preventive action (CAPA) and audits. MasterControl also offers a manufacturing solution called MasterControl Manufacturing Excellence. It is a suite of proven technologies that optimizes the side-to-end lifecycle of manufacturing and easily integrates with other enterprise software such as MRP, MES, ERP, MOM and production schedules.

28. Fishbowl Manufacturing

Fishbowl is a platform for business development and inventory management for smallto mid-size businesses. This combines with QuickBooks accounting and provides inventory control, preparation of material requirements (MRP) and execution of laboratory floor control / manufacturing. It is an inventory-centered framework, with barcoding, asset management, raw materials control, process counting and custom reporting functionality. The program also automates the procedures for pricing, purchasing, and buying. It also combines accounting, distribution, e-commerce and retail services with third-party services.

29. Intellect eQMS

Intellect eQMS is a customizable organizational quality management solution based on the cloud that helps companies across different industries monitor the quality and compliance of critical business processes. This requires monitoring of records, management of reports, nonconformance, management of changes and more. Intellect eQMS is established on the IC Platform, Which enables un-programmers to edit or construct new business applications using drag & drop technology. It allows users to create, monitor and maintain records of conformance ensure compliance with records of management and delegate follow-up tasks for corrective and preventive actions (CAPA). The software also helps users monitor customer complaint intake, centralize record incidents to promote analysis, report results, and close cases.

30. Oracle JD Edwards – Manufacturing

Oracle JD Edwards EnterpriseOne is a web-based Enterprise Resource Planning (ERP) and supply chain management system that offers ERP software and tools for banking, goods, human resources, supply and manufacturing sectors. It provides for small, medium-sized and large businesses. Primary features include financial management, project management, asset lifecycle management, order management, CRM, manufacturing, logistics and supply chain planning, reporting, and business intelligence. It allows users to manage various production operations through lean and project-based modes of manufacture.

CONCLUSION

In this review article we introduced various computer system software useful for regular cGMP practices like manufacturing, documentation, etc. were followed in the pharmaceutical industry. This article also covers the current and future need of pharmaceutical industry for software. There are some common softwares which has been used in organization, quality control area, research and development, storage, resource and generation, in all disciplines of engineering and architect, management, pharmacy and agriculture. The listed softwares are specially used in pharma sectors and most useful for problem solving, data integrity issue, creating tamperproof audit trial, data backup and restoration.

REFERENCES

1. Mannam A, Mubeen H "Review Article Digitalisation And Automation In Pharmaceuticals From Drug Discovery To Drug Administration" international Journal of Pharmacy and Pharmaceutical Science 10(6), 2018 May 8, 1-10.
2. Mali P Y, Panchal S J "A review on worldwide essential software resources in Pharmacy" Chronicles of Young Scientists 2(1), 2011, 11-20.
3. Victor DeCouto, Singh S. "Electronic Validation in the Pharmaceutical Industry" (2016). Mathematics and Computer Science Capstones. 28. La Salle University La Salle University Digital Commons. http://digitalcommons.lasalle.edu/mathcompcapstones/28
4. Upadhyay P. The Role of "Verification and Validation in System Development Life Cycle" IOSR Journal of Computer Engineering 5(1), sep-oct 2012, 17-20.
5. Jukka R, Johannes K "Review The Future of Pharmaceutical Manufacturing Sciences" Journal Of Pharmaceutical Sciences 104:3612–3638, 2015 Published online 2015 August 17 in Wiley Online Library (wileyonlinelibrary.com)..
6. Hoffmann A, IGihny-Simonius J, Marcel Plattner , Vanja Schmidli-Vckovski , Kronseder e C "Computer system validation: An overview of official requirements and standards" Pharmaceutics Acta Helvetiae, 72, 1998, 317-325.
7. GAMP 5 – Good Automated Manufacturing Practices, Version 5, Guideline document for automated systems from International Society of Pharmaceutical Engineering.
8. https://softwareconnect.com/manufacturing/virtual-office/
9. https://www.softwareadvice.com/manufacturing/pharmaceutical-manufacturing-software-comparison/
10. https://www.softwareadvice.com/manufacturing/pharmaceutical-manufacturing-software-comparison/

Source of Support: Nil, **Conflict of Interest:** None.