eBR for Paperless Manufacturing in the Pharma Industry

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1. The pharmaceutical industry operates under stringent regulatory requirements. How does the adoption of eBR systems assist pharmaceutical manufacturers in achieving and maintaining compliance with regulations like FDA 21 CFR Part 11 and EU Annex 11? What specific features of eBR systems contribute to compliance efforts?

eBR systems are more reliable and compliance than traditional paper documents, log in measures, electronic signature, e-traceability, are only a few of the key advantages of digital records over paper-based ones. Regulators and inspectors prefer by far these new technologies when they perform regular audit visits to our companies.

2. The transition to paperless manufacturing through eBR implementation requires robust data security measures. How can pharmaceutical companies ensure the confidentiality, integrity, and availability of electronic batch records? What strategies are employed to protect against potential cyber threats and data breaches?

The support of a strong IT group in our pharma companies is essential. This group must make proper cyber risk assessments to ensure the security and integrity of the e-systems protecting them from internal and external attacks. At the end it as not different from the safety of e-banking systems as an example of a few.

3. In the context of the pharmaceutical supply chain, how does the integration of eBR systems with Enterprise Resource Planning (ERP) and Manufacturing Execution Systems (MES) facilitate real-time data exchange and decision-making? How does this integration optimize overall supply chain efficiency?

In the current hard supply chain environment that we have in our pharmaceutical

industry in these post-pandemic years, the integration of all our systems is critical to achieve success in all our production sites. Sales forecasting, stocks, lead times of the suppliers, etc. must be fully available, and with online time refresh, to give the right inputs to supply chain professionals so they can make the right and accurate decisions to assure WW pharma supply chain, essential to ensure also the right treatment to all patients that needed.

4. The pharmaceutical industry often deals with complex and highly regulated manufacturing processes. How do eBR systems assist in automating and standardizing workflows to improve operational efficiency and reduce errors during batch execution?

The electronic systems have a lot of right features to decrease errors in manufacturing execution, for example, auto-corrections, auto dating and timing, a list of choices so you avoid mistyping, etc. All these systems assure data integrity and avoid mistakes. Of course, the more efficiency of the process is assured through them, as we can see in different KPIs we monitor across our production sites.

5. Continuous improvement is vital in pharmaceutical manufacturing to enhance product quality and ensure patient safety. How can eBR systems aid in monitoring and analyzing manufacturing data to identify trends and potential areas for improvement? Share examples of how this data-driven approach has led to process optimizations.

You can use different continuous improvement systems, like Kaizen, Six Sigma, etc. but all of them can take profit from eBR systems. We are also nowadays performing a big Quality Culture program in the company, that takes some inputs in a direct way from our e-systems, including eBR of course also.

6. In a global pharmaceutical manufacturing setting, companies may have production facilities across different countries. How does the use of eBR systems enable seamless collaboration, data sharing, and standardized processes among geographically dispersed sites while adhering to regional regulations?

Today the full harmonization between your different production sites, in the same or different countries, is critical. Regulators like the FDA expect Quality Oversight between all your production sites, you only need to see some of the last Warning Letters on their WEB. In our case we have production sites in two different countries and electronic systems, like document management systems for deviations, change control, CAPA follow-up, etc., and eBR for online data sharing are pillars of this objective.

7. Data integrity is a critical concern in the pharmaceutical industry. How can an eBR system provide an audit trail for all data and actions, ensuring transparency and traceability throughout the manufacturing process? How does this audit trail support regulatory inspections and internal quality audits?

A reliable audit trail system that assures log-on follow up, electronic signature, date and time monitoring is essential to assure the correct performance of all electronic programs in our company. They are also a key factor for inspections and audits success, as inspectors focus in these points most of the data integrity findings.

8. With the increasing adoption of advanced technologies like Artificial Intelligence (AI) and Machine Learning (ML) in manufacturing, how can eBR systems leverage these technologies to enhance process efficiency, predict potential deviations, and support real-time decision-making?

We think so, but honestly, we do not have so much experience yet in AI or ML to give a solid feedback to our colleagues.

9. As the pharmaceutical industry moves toward personalized medicine and smaller batch sizes, how can eBR systems adapt to these changing manufacturing needs? Discuss the flexibility and scalability of eBR systems in meeting the demands of modern pharmaceutical production.

Absolutely, electronic systems are much more flexible and adaptable ones, that traditional paper based. Time to change an scale up as example that is very common in our industry could be cutted 2 or 3 times manging the change electronically, this advan-

tages apply also to other common changes in our industry like new line validation, variable processes changes, etc.

10. Validation is a crucial aspect of eBR implementation. How can pharmaceutical companies ensure the validation and qualification of eBR systems meet regulatory requirements? What challenges might arise during the validation process, and how can they be effectively addressed?

IT groups in our companies must be fully trained and qualified in quality systems validation requirements, GAMP rules and FDA (EU expectations. Then they must roll out in the organization a correct IT control change sytem to assure full compliance during all the time of operation of the site. The new role of the IT compliance officer is key in the success of this task, find a right person in this position is crucial.

11. As pharmaceutical manufacturers implement eBR systems, employee training and adoption become essential. How do companies ensure that the workforce is adequately trained to use eBR systems effectively? What strategies are employed to overcome resistance to change and promote user acceptance?

We have now the advantage that the digital have become familiar in day-to-day life, e-banking, mobile phone apps, auto parking cars, etc, are present all days in our lives, crossing our normal activities. So workers and employees are now not so reluctant to e-sytems, as like to be in the past some years ago. But we still need to use some strategies to close our people to new tech-

nologies, the support of a good HR department is very important for that, we make some special programs that sometimes are not more than like “funny games”, but very effective to close the e gap, and make the induction process to the electronic world much softer.

12. The pharmaceutical industry is moving toward a more data-driven approach to quality management. How does the integration of quality control and quality assurance processes with eBR systems facilitate real-time monitoring of critical quality attributes and enable early deviation detection?

Electronic systems, not only in production like eBR, but also in quality control labs like LIMS systems, allow online monitoring of all process variables, and of course, alarms associated, that never sleep or lunch, and could prevent mistakes or implement quick early corrections, avoiding a lot of future problems and costs. Traditional paper based-systems never could make this happen in this efficient way.

13. Continuous auditing is gaining traction as an alternative to traditional periodic audits. How can eBR systems support the concept of continuous auditing in pharmaceutical manufacturing, providing real-time insights into compliance and quality performance?

We do not have yet real experience in continuous auditing, but of course, seems something possible in view of all we have discussed in the last questions. As we have made possible virtual inspections during the pandemic, and now are normal stuff for all of us, I imagine that this continuous auditing concept will be standard in the short future in our industry, improving compliance and q performance by sure.

14. Lastly, what are the future trends and innovations in eBR systems for the pharmaceutical industry? How do you envision eBR systems evolving to meet the dynamic needs of the industry in the coming years?

Systems in general are evolving to pure friendly user interfaces, and in some cases, you are not even aware that you are interacting digitally, instead of analogically. This is the trend, the use of AI tools like chatbots, and the penetration of digital systems in our industry will be unstoppable.

AUTHOR BIO

Gustavo Samojeden is currently working as the CEO of Eriochem S.A. He is a Pharma executive with more than 35 years of experience in both technical and business aspects of the industry. Has managed C-level organizations in 5 countries on 3 continents with a focus on emerging markets like South East Asia Pacific and Latin America.