



# MAKE 2020 THE YEAR YOU START USING THE AVAILABLE TECHNOLOGY

by John Johnson and Tony Margetts

We are constantly researching and engaging with other industries, learning how they became successful, deep diving into the technologies, systems and behaviors that make the world's best companies more successful.

One aspect that comes up constantly is that other industries are deploying new technologies and applications faster than we are in the pharma industry. Of course there are notable exceptions, and some of our leading multi-nationals have deployed systems like quality by design, LIMs, e-QMS and electronic batch instructions and records (EBIR), but it is still notable that across the world many of our clients are using paper-based systems and minimal modern technology across the factory. There are several reasons for this, but do any of those reasons outweigh the huge benefits to GMP compliance, right first time, data integrity and adherence to standard instructions? Why is our industry lagging in deploying modern technology in key areas, and isn't 2020 a good time to start to consider researching what options are available to define, control, monitor, automate and record our production and quality processes?

Providing it is defined and deployed carefully and with intensive user input, the use of EBIR can be transformational to your business. NSF worked with a client recently to transform the paper-based SOP system to a video link tablet-based system with great effect. We are also researching how Google's smartglass solutions could be deployed to define and monitor pharma processes.

**Tony Margetts from FactoryTalk describes alongside how EBIR can be used to transform performance and compliance in pharma processes.**

## ELECTRONIC WORK INSTRUCTIONS A USER CASE FOR NEW MANUFACTURING APP TECHNOLOGY

### WHAT ARE ELECTRONIC WORK INSTRUCTIONS?

Electronic work instructions (EWI) help eliminate paper procedures and forms on the shop floor to improve standardization, enable stronger operator guidance, and speed up and increase the accuracy of manual activities in production areas. Manufacturing applications (apps) are web-based software tools that are easily and rapidly configured to model process steps and sequences without the need for a large and costly IT system implementation and they do not require software development.

Apps are made available through tablet computers. These can be easily taken onto the shop floor and make use of simple dialogs and user interaction to record data that allow for greater visibility of the operation to other operators and managers. Any issues and errors can be dealt with immediately and notifications are built in using email for automating communication around the factory.



## ADVANTAGES/OBJECTIVES OF USING EWI

EWI have already been widely used across various industries, and:

- > Provide clear and repeatable instructions to operators
- > Allow efficient update of procedures by online collaboration and using good document practice
- > Ensure the latest instructions are being used and distributed across the facility
- > Can include content rich multimedia (e.g. photos, video, audio) in the instructions
- > Improve collaboration between operators, engineering teams and management
- > Communicate changes immediately
- > Are easily extended for adopting a culture of continuous improvement
- > Correct errors in real time
- > Collect data easily and make this available to all in dashboard and analytics
- > Allow real-time audits
- > Easily create effective training material
- > Greatly reduce training time
- > Reduce waste, errors and delays in manual operations

The pharmaceutical industry has been slow in picking up advances in the IT area because of concerns about change management and compliance with regulations. EWI represent a clear improvement in ways of working which do not conflict with the regulations if they are deployed in a controlled manner. It is possible to start with existing approved instructions (SOPs), systemize these and extend with additional content using collaboration and good document practice.

In training, EWI provide stronger guidance and are more intuitive and quicker to train new staff using interactive apps than with paper. The tool used for training is the same as that found in production, so

training is hands-on and closer to real life, but training can be done offline before progressing to working in production with more experienced staff able to easily watch what is happening.

## HOW DO EWIS FIT INTO THE EXISTING LANDSCAPE?

Much of the software in today's factories is static. An example is an ERP system developed by an outside company to work in a broad range of factories. It is implemented from the top down by executives who know software can help, but don't know how best to adopt it. It may take three years to deploy all the planned functionality, and the result is often that users get screens that everyone isn't really happy with because they solve yesterday's problems.

Manufacturing apps provide a different, bottom-up approach that is solely aimed at rapidly bringing what the operators on the shop floor actually need: a configurable manufacturing platform that connects people, machines and sensors to help optimize processes. They can be deployed in a highly flexible manner allowing apps to be installed at just one workstation to gain immediate benefits and then be scaled up and out as needed.

## SUMMARY

EWI apps are an engine for manufacturing improvement and a major advance with a number of important consequences for production operations:

- > Apps offer a refreshing and flexible bottom-up approach to IT as a low-cost solution to focus on helping operators do a better job without mistakes.
- > Apps are designed to be human friendly to guide and report on important operations in a way that fits into the workflow.
- > The apps guide operators and record all needed actions electronically with automatic time stamps and audit trails.
- > Process information recorded can be extended to include live photos and video so more complete data can be captured.



- > Managers can monitor data in dashboards, see the current status of important processes and better communicate with their operators through electronic means without having to constantly be available on the line.
- > Defects and mistakes are captured in real time and can be corrected before they result in waste.
- > Apps can be deployed in days at lower cost than existing manufacturing IT solutions to bring and demonstrate benefits quickly.
- > EWI apps are simple and intuitive and built with building blocks like PowerPoint. They are version controlled and distributed to stations on the production line.
- > Typical improvements are:
  - Increased right first time by reporting defects at the source
  - Higher throughput
  - Standardization of manual processes
  - Faster training times
  - Real-time reporting on KPIs

**In conclusion, manufacturing apps help to build quality in without the need for total automation so manufacturers can continue to best utilize people to optimize their processes. In the Industry 4.0 age, empowering the workforce is a critical aspect of digitization.**

**So, our question remains, you wouldn't use a mobile phone designed 20 years ago (or even two years ago), so why not start employing new technologies to solve age old issues? The millennial generation will demand new ways of learning, new ways of adding value and new methods of automating repetitive processes, so perhaps it's time to start looking at new technologies.**

## ABOUT THE AUTHORS



**John Johnson** is passionate about helping organizations foresee and overcome the barriers to sustainable long-term growth. He brings 28 years' experience across a range of companies in the pharmaceutical and healthcare industry.

He has worked in small, medium and large pharma biotech companies across the product lifecycle for a wide range of dosage forms.



**Dr. Anthony Margetts** is Principal Consultant for Factorytalk's Compliance department. He is a global expert in the fields of GMP compliance and validation with 30 years' working experience in the pharmaceutical, medical device, and regulated industries. Dr. Margetts has also been involved in producing several of the GAMP/ISPE good practice guides including leading roles in GAMP5, and recent document "The ISPE Good Practice Guide to Electronic Record & Data Integrity" which was published in 2017.

For more information, contact [pharmamail@nsf.org](mailto:pharmamail@nsf.org) or visit [www.nsfpharma.org](http://www.nsfpharma.org)

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## NSF INTERNATIONAL | PHARMACEUTICAL SERVICES

The Georgian House, 22/24 West End, Kirkbymoorside, York, UK YO62 6AF

**T** +44 (0) 1751 432 999 | **E** [pharmamail@nsf.org](mailto:pharmamail@nsf.org)

789 N Dixboro Rd, Ann Arbor, MI 48105, USA

**T** +1 202 822 1850 | **E** [healthsciences@nsf.org](mailto:healthsciences@nsf.org)

[www.nsf.org](http://www.nsf.org) | [www.nsfpharma.org](http://www.nsfpharma.org) | Follow us on [LinkedIn](#) & [Twitter](#)