

## THE NEXT INDUSTRIAL REVOLUTION – PHARMA 4.0



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By

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Karen Ginsbury recently guested on "Voices in Validation" podcast and share her insights on the pharmaceutical industry and the implementation of prevailing technologies. Traditionally an industry slow to accept change, it is now apparent that drug makers will need to not only embrace advanced technologies but develop a plan to implement or risk extinction. The following points were part of our discussion and offer opinion on timing and impact across the pharmaceutical industry.

### **What is Pharma 4.0?**

Essentially, it is the 4th "industrial revolution" which will require the analysis and integration of the data – BIG DATA – building on the 3rd industrial revolution, computerization.

More specifically, the fourth industrial revolution (4IR), or industry 4.0 for the Pharmaceutical industry can be thought of as a combination of cyber physical systems, the Internet of Things (IoT), and the Internet of Systems. This is already happening, for example "Smart Factories" where machines are augmented with web connectivity and connected to a system that can consider the entire production chain and make decisions on its own, as the one Novartis has created.

<https://www.novartis.com/stories/discovery/new-drug-manufacturing-tools-change-pharma-chemistry>

### **The IoT**

The Internet of Things, or IoT, is a comprehensive network of connections. This links of "things" exists between people - people, people - things, and things – things.

Think of mobile telephones, people connect with other people via standard voice calls, text messaging, video chats, air dropped photos, etc. Most of us are always connected, think about wearable devices – like your Fitbit or Apple watch. We rely on the automated and integrated technologies throughout our homes, controlling temperature, lighting, appliances, and security systems. If it has an on/off switch, then chances are it can be a part of the IoT.



### Defining Big Data

A collection of information, or data, which can come from a variety of different sites – may be structured or unstructured in nature. These extremely large data sets may be analyzed computationally to reveal patterns, trends, and associations, especially relating to human behavior and interactions. This is especially important in predictive medicine as we strive to create more personalized solutions to human health challenges. This directly impacts pharma manufacturing. As continuous production of drugs for smaller groups of people becomes patient centric, flexible and delivers more precise product and dosing. This can happen because of the constant feedback gained from data collected, and real time analysis.

The importance of big data is not HAVING IT, but IN USING IT! It does not matter how much data you have, or are able to collect, unless it helps influence decision. In pharma, what you do with data from any source must be analyzed to enable, cost reduction, time efficiency, new product development and optimized offerings, and smart decision making.

For more information on continuous manufacturing in pharma see

[https://en.tefen.com/insights/services/Manufacturing\\_Quality/the\\_impact\\_of\\_industry\\_40\\_on\\_the\\_pharma\\_industry](https://en.tefen.com/insights/services/Manufacturing_Quality/the_impact_of_industry_40_on_the_pharma_industry)

### **Blockchain – what, why and how?**

What is block chain? A blockchain is a growing list of records, called blocks, which are linked using cryptography. Each block contains a cryptographic hash of the previous block, a timestamp, and a transaction. By design, a blockchain is resistant to modification of the data. That's right – built in data integrity.

Why aren't we using blockchain? Why don't we even understand it? This technology is considered disruptive in food, finance, and goods production, as the utilization provides solutions to common manufacturing mishaps. Inherent in the technology, blockchain provides a digital ledger that records, stores, and tracks data, thereby providing a way to monitor the supply chain and detect contamination issues, for example. It is also completely transparent, as every transaction is linked to a user and cannot be modified after the fact.

For more on blockchain see a previous blog by Tim Sandle. <http://www.ivtnetwork.com/article/blockchain-innovations-pharmaceuticals-and-healthcare>

### **Obstacle to Implementation**

It would stand to reason that all these technologies stand to provide positive impact on the pharma industry. Why so slow to adopt? The number one reason – FEAR.

In an industry where patient lives matter, and validation of equipment and processes prevail, it is scary relinquishing oversight to computers and machine learning. Very real concerns exist over Cybersecurity, loss of internet or wireless transmission, data incompatibility, and so on... The bottom-line remains, Pharma 4.0 will increase efficiency, reduce costly processes, minimize human error, and allow for much more personalized care – thereby increasing patient access. But it does not happen overnight and must be the result of a well-organized thought through plan.

All companies in the pharma industry must begin on that plan today. In the next five years any company who is not already planning, implementing, and revising will be eliminated from play.

*This blog is a summarized version of ideas shared with IVT Network via presentations and podcast recordings with Karen Ginsbury. Any ideas or opinions should be viewed as such and should be used only as a basis for further inquiry or independent research.*

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