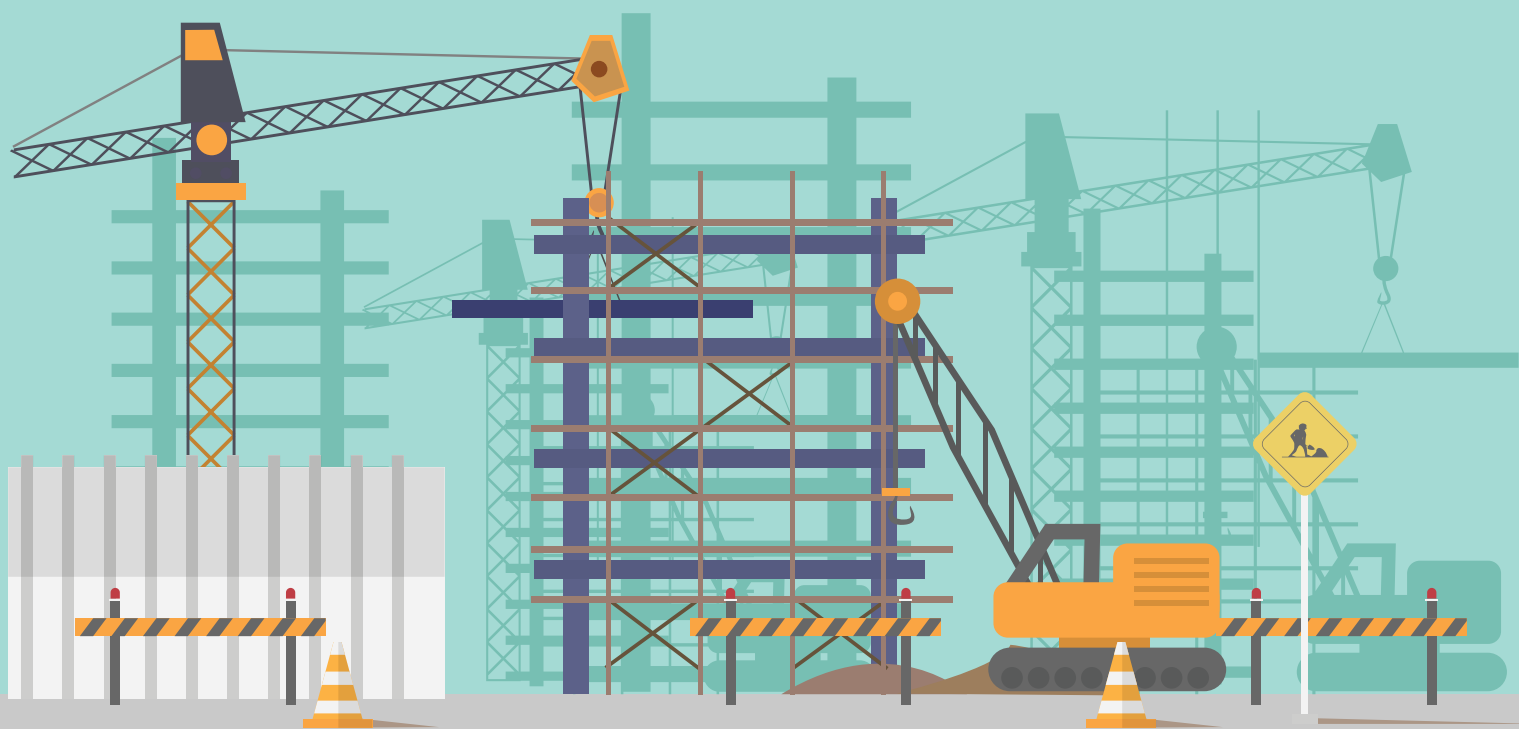


## ONYX - Algeria

### Overcoming challenges by re-imagining solutions



- + **PHARMA ACCESS & ONYX:**  
Overcoming challenges by re-imagining solutions.
- + **Pharmaceutical Data Integrity:**  
A 'do-or-die' situation for the sector.
- + **PHARMA 4.0:** Designing future ready Pharma facilities.

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## Pharma Access Fact File



### PHARMA ACCESS & ONYX: Overcoming challenges by re-imagining solutions.

ONYX is our project in Annaba, Algeria that is nearing completion. It is a success story that we at Pharma Access take immense pride in. During the course of this challenging project we overcame problems with innovative design solutions.

Right from space constraints, complex existing structure (curved roofing hanger) & restriction to use existing structure; the project faced a multitude of challenges.

The project was designed & developed in two separate hangars connected by one small air-lock. So, designing a facility with proper man & material movement as per GMP was another challenge.

We have succeeded in reducing floor space required for Onyx by almost 60% when compared with initial conceptual design thus saving lot of energy costs on HVAC & electrical disciplines.

We have used solar reflective paint for roof painting so that the roof doesn't get heated up, and only negligible heat is radiated inside the hangar creating comfort to occupants and reducing HVAC load. It also helps a lot for saving energy & cost.

We have worked with a reputed foreign structural consultant & co-ordinated his designs & local material availability.

The electrical power receiving & distribution system has been another tough task to handle. With the type of curved roofing hanger, the panel positioning, cable trays, cabling has been a challenge. Similarly, low voltage cabling too was an hurdle we overcame.

The logistics and support of main ducts, main piping headers, light fixtures, cable trays, modular clean room ceiling hanging arrangements & supporting system was also not the run of the mill work. We could even undertake some modifications in electrical & mechanical systems to accommodate changes proposed by client at a very late stage.

Moreover, our dedicated team has gone and carried out timely execution of this project as per schedule till date. Because, at Pharma Access we believe that problems cannot stop us from delivering on our promises.

### KEY ACHIEVEMENTS

- Reduced Floor space required for project by almost 60%
- 100+ vendors coordinated with
- 20+ sub-contractors worked with
- Solar reflective paint for roof painting
- Cost & Energy Saving

## BIG Pharma Centrestage

### Pharmaceutical Data Integrity: A 'do-or-die' situation for the sector.

The global pharmaceutical industry is undergoing multi-faceted changes. With data ruling the game ahead in all sectors, the need for data integrity in pharma field has gained a momentum.

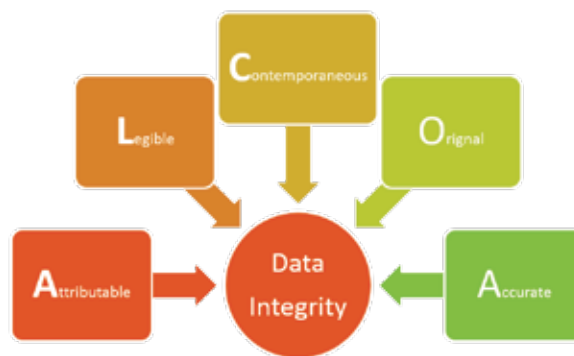
The current tide of changes in global pharma industry has turned the focus of almost every agency in the pharma sector to ensure the integrity of all data associated with the manufacturing and testing of pharmaceuticals.

For the end products meet the required quality standards, experts have realized the importance of data integrity. It is the process of maintenance and assurance of accuracy and consistency of the data over its entire life cycle.

In order to maintain data integrity, organizations must safeguard it from accidental or intentional modifications, duplication, deletion and falsification. While purposeful data adulterations do occur, many data integrity violations are not purposeful and are a result of improper training, ineffective SOPs, corrupt systems, or lack of clarity within the regulations.

The global regulatory bodies such as the Medicines & Healthcare Products Regulatory Agency (MHRA), the U.S. Food & Drug Administration (FDA), Pharmaceutical Inspection Co-operation Scheme (PIC/S) and the Australian Therapeutic Goods Administration (TGA) have emphasized the importance of accurate and reliable data in assuring drug safety and quality. FDA and MHRA have released new cGMP guidelines for 2017, which aim at raising the focus on data integrity.

### ALCOA: FDA's Data Integrity Focus



All of the major guidance documents refer to the ALCOA principle for defining the high level requirements for ensuring data integrity.

**ALCOA is an acronym representing the following data integrity elements:**

- + Attributable – Who performed and when?
- + Legible – Can it be read? Permanent Record
- + Contemporaneous – Recorded at the time the activity was performed
- + Original – Original record or certified true copy
- + Accurate – Error free

Data is the key to effective decision making, continuous improvement, quality, and the demonstration of clinical value must hold high levels of integrity regardless of the regulatory environment. However, with regulatory bodies taking up the subject seriously, it is crucial that organizations now give more importance to monitoring data life cycle and secure data integrity at all costs.

In sync with this, we at Pharma Access, supply all equipment compliant to 21CFR Part 11, which help in maintaining electronic records, hence preserving data integrity.

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## PharmaXChange



### PHARMA 4.0: Designing future ready Pharma facilities.

The pharma industry is rapidly evolving. Today, at the core of every pharma company is the goal to create value for both the industry itself and the patients that rely on targeted drugs it manufactures. Pharma 4.0 is an initiative that is strongly reflective of this evolution. But what exactly is Pharma 4.0 all about? Let us find out.

#### Pharma 4.0: The Origin

The term Pharma 4.0 refers to the industrial revolution with regards to modern information and communication technology. Throughout the industry, Pharma 4.0 stands for promising and feasible approaches for the Pharma World, one that denotes a highly regulated environment and, at times, ever-higher barriers to change.

#### Objectives of Pharma 4.0

One of the core objectives for Pharma is making businesses more safe and efficient. The areas of vital importance are the data integrity with the aiming to generate right data available in the right quality, at the right time, and in the right place. The shared target of every agency involved is to achieve improved quality, efficiency and, consequently, overall success of the pharma value-chain.

#### Future-ready facilities

Compared to other initiatives on the industry radar, the mission to revolutionize the pharma and biotech industry by helping to make it safer and far more efficient is gaining momentum globally. Pharma 4.0 is a next big leap on the journey of revolutionizing the pharma industry. It essentially means focusing on tasks such as the handling and usage of the gained results and data in a more comprehensive and functional manner than in the past. Pharma facilities have to realize their responsibility in supporting the needs of its customers in developing devices and processes that contribute to increased patient safety, convenience, and enhanced compliance.

**To know more about the Futuristic Facilities, Visit our Stall atACHEMA- Hall 3.1 J48**



**PHARMA ACCESS - OVER 17 YEARS OF DELIVERING EXCELLENCE TO THE PHARMACEUTICAL SECTOR**

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