MSb

SMART DOCUMENT SOLUTIONS

GxP
COMPLIANCE
& VALIDATION

How Going Paperless
Saves Your Time, Money
& Efforts

2020

What is GxP?

GxP is a general abbreviation for the "good practice" quality guidelines and regulations that were established in the U.S. by the Food and Drug Administration (FDA). The overall intent of these guidelines and requirements is to ensure that medicinal products, medical devices, biologics, and other food products are safe for consumption. In addition to this, there are regulations set to ensure the integrity of data used to make product-related safety decisions.

GxP Validation

In order to accelerate production and innovate new products, manufacturers of life sciences industry adopted digital practices. The manufacturers are now rapidly optimizing medical devices and products manufacturing processes. With this, the usage of computerized systems is on hike. These computerized systems need to undergo proper validation process. And under the Gxp regulatory compliance, this validation is referred to as GxP validation.

Traditional Way to Carry out GxP Regulated Processes

The traditional way of meeting these regulations was by carrying out paper-based processes that, too, manually. This results in complicating new product introduction pipelines in the life sciences industries. Many companies are left behind the competition while continuously failing to deliver a safe and effective product.

Challenges That Regulated Industries Face

Regulated industries face challenge in focusing on the following key areas as most of their productive hours are wasted on paper-based manual processes.

ACCURACY

TRACEABILITY

INTEGRITY

AVAILABILITY

ACCOUNTABILITY

Ideal Solution That Digital Era Brings In

The rapid digital advancements made quality manufacturing a simple process. The ideal solution is eliminating paper production records and digitizing the process. Almost every organization is now undertaking such practices as these regulations holds the potential to make or break a business.
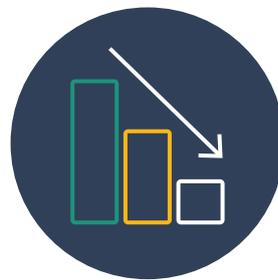
Added Value by Going Paperless

2-3 HOURS
PAPER-BASED PROCESSES

10-15 MINUTES
PAPERLESS PROCESSE

TIME SPENT IN CHANGES & CORRECTIONS

90%
DESCREASE IN PRODUCTION ERRORS

30%
INCREASE IN EFFICIENCY

How MSB Docs Fits In?

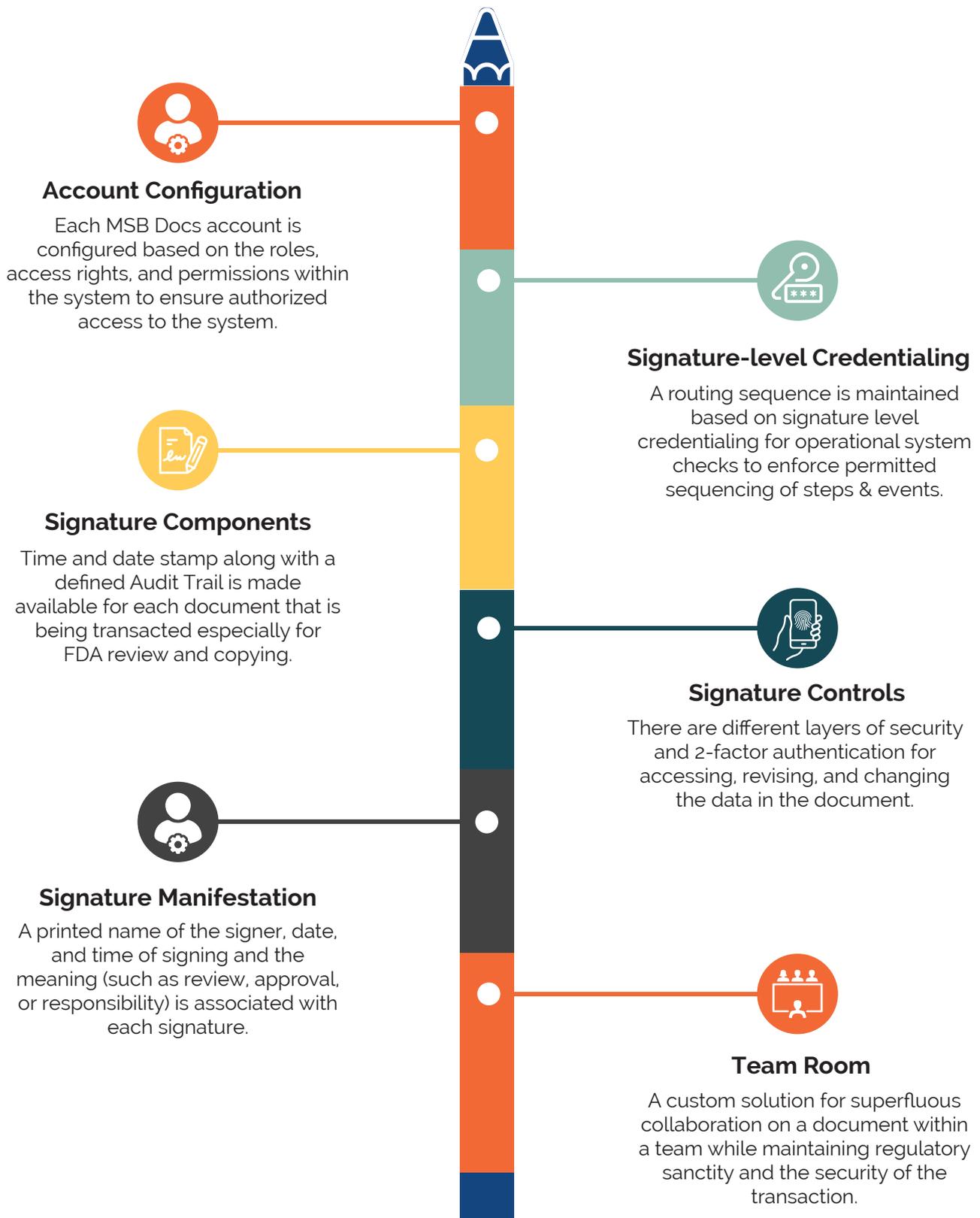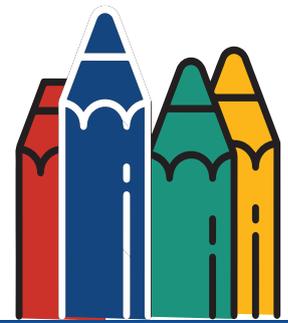**MSB Docs –** as a smart document solution, makes GxP compliance easier than ever. All the manufacturing, testing, and validating processes go paperless with MSB Docs.

Be it manufacturing, testing, or validating processes, today life sciences industries are switching to paperless processes. With this, many pharmaceutical giants like Pfizer, Roche, GSK, ICON made MSB Docs their choice.

GxP

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What Makes MSB Docs Stand Out from The Crowd?

MSB Docs implements a secure and easy to use smart document solution that comprises of following industry-designed capabilities. All these helps our clients for staying compliant with GxP regulations.

Account Configuration

Each MSB Docs account is configured based on the roles, access rights, and permissions within the system to ensure authorized access to the system.

Signature-level Credentialing

A routing sequence is maintained based on signature level credentialing for operational system checks to enforce permitted sequencing of steps & events.

Signature Components

Time and date stamp along with a defined Audit Trail is made available for each document that is being transacted especially for FDA review and copying.

Signature Controls

There are different layers of security and 2-factor authentication for accessing, revising, and changing the data in the document.

Signature Manifestation

A printed name of the signer, date, and time of signing and the meaning (such as review, approval, or responsibility) is associated with each signature.

Team Room

A custom solution for superfluous collaboration on a document within a team while maintaining regulatory sanctity and the security of the transaction.

Thank You!

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