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Every day, businesses in the pharmaceutical industry must be ready to manage any number of different challenges where any resulting equipment downtime can severely affect drug production and quality.



Constantly-changing regulations

Severe production environment difficulties

Complex, difficult to maintain equipment



Introduction 2/2

When it comes to pharmaceutical manufacturing, sticking to **production schedules can be incredibly demanding** on equipment and machinery that needs to be constantly in operation.

Around the clock, organizations are hard at work to ensure maximum availability of their assets in order to achieve a certain level of **production efficiency.** This competitive production environment requires equipment to perform at full capacity with no downtime.



Organizations looking to maximize efficiency should be aware of key points that present a clear picture of the current state of plant equipment and manufacturing in general.

20 yrs

50 bn

5-20

%

Around three-quarters of all the plant equipment in manufacturing is more than **20 years old**, which says a lot about the quantum of obsolete equipment and highlights a significant cause of production downtime.

Unplanned downtime is costing industrial manufacturers an estimated **\$50 billion** each year.

Poor equipment maintenance strategies can reduce a plant's overall productive capacity by **5 to 20** percent.



Understanding equipment downtime, reliability and availability

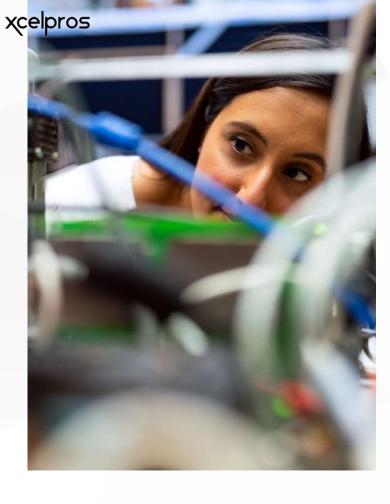
For manufacturers in the pharmaceutical industry, having **fully functional equipment is of utmost importance** and means their business can operate normally.

Understanding things like **downtime, reliability and availability** can be just as important if not more.

Scheduled Downtime is important for changeovers, cleaning, tool changes, early shutdowns, personal breaks, or any unplanned events that may occur, such as breakdowns or any repairs that can affect the core business.

Equipment reliability is the health of equipment and how optimally it performs a task, taking into consideration attributes like quality and performance.

Equipment availability is the actual time that a machine or system is available for production as a percent of total planned production time.



Downtime, reliability and availability aren't the only things these businesses deal with

Spiking maintenance costs

This usually results in businesses reducing maintenance which can lead to complete failures, severely impacting revenue and operations.

Drug safety risks

As equipment ages it becomes easier for contamination to occur, which could lead to additional damages.

Increased downtime

This can lead to Supply chain disconnects, lower production, missed deadlines and increased penalties.

Equipment repair

Without a preventative maintenance plan, businesses are required to perform repairs as needed. This leads to uncertainty when it comes to the status of equipment and prolonged downtimes.

Low quality drugs

Unreliable or under-maintained equipment can unknowingly produce lower quality products leading to fines, penalties and costly recalls.

Loss of reputation

Missed deadlines, poor quality and unsafe products can have a severe impact on revenue and brand reconition.

Equipment replacement

Upkeep is always cheaper than replacement. When equipment isn't properly maintained replacement costs can easily end up exceeding the total costs of having a basic maintenance plan on board.

Production dips

Usually caused by gaps in asset or equipment availability, this can halt production and affect the company's revenue.



Understanding equipment downtime, reliability and availability

A big reason this all matters stems from the U.S. Food and Drug Administration's (FDA's) decision to **include equipment maintenance as a risk-based preventive measure** in Current Good Manufacturing Practices (cGMP).

With the USDA considering equipment maintenance as a key function of cGMP, it easily becomes one of the most critical factors for pharmaceutical manufacturers' compliance and will be subject to even greater scrutiny.





A game-changer in the pharmaceutical industry

More and more organizations are finding it easier to control their machinery and minimize

"time-to-insight" with Microsoft

Dynamics 365 capabilities designed to help businesses gain total control of their data, offering integrated analytics and workflows.

Microsoft Dynamics for pharmaceutical companies lets businesses speed up the movement of goods, eliminate waste due to costly shelf-life expirations and returns, and improve production efficiency across their entire line.



A **game-changer** in the pharmaceutical industry

Microsoft Dynamics for pharmaceutical

gives companies the ability to achieve the following:

Ensuring centralized Quality Control (QC) and regulatory support

Organizations can use integrated quality controls and lot traceability to link raw materials through each operation of the production process. This helps accelerate and simplify compliance with regulatory agencies such as the U.S. Federal Drug Administration (FDA).

Managing inventory more effectively

Pull inventory in sequence, utilizing "best before" management, and enabling customer service to ship lots that arrive with the correct amount of shelf life remaining. Employ either first expiry/first-out (FEFO) or first-in/first-out (FIFO) calculations for inventory reservations, picking, reducing inventory and eliminating waste.



A game-changer in the pharmaceutical industry

Microsoft Dynamics for pharmaceutical

gives companies the ability to achieve the following:

Conducting extensive audit trails

Incorporate electronic signature functionality into existing business processes, providing complete visibility into batch production and audit trails.

Meeting GMP requirements

Manage electronic quarantines, quarantine release by user & material type, printed material/ obsolete component controls, lot control/ segregation, lot tracking, drug and hazardous material reconciliation, and more.

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A **game-changer** in the pharmaceutical industry

Microsoft Dynamics for pharmaceutical

gives companies the ability to achieve the following:

Improving production planning

Accurately model the processing of costly ingredients to help **minimize overruns and underruns.** Shelf-life planning helps account for expiration dates during production and distribution.

Protecting recipes and formulas

Dynamics 365 helps document various ingredients, storage requirements, manufacturing processes, pH values, particle size, and much more – all with the ability to review at any given moment.

D365 lets you set security restrictions to ensure that only approved users are able to make changes, further protecting your critical assets.



Final Thoughts

As the pharmaceutical industry continues to evolve and grow, the need to understand and adopt **intelligent technologies like Dynamics 365 becomes more and more apparent**. Implementing solutions like Microsoft Dynamics 365 for pharmaceutical and other.

Pharmaceutical manufacturing ERP softwares is the best way for companies to maximize their asset availability and track machine reliability, letting them drive towards increased productivity, higher quality products and enhanced safety assurance.

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