

Microsoft Dynamics AX for Life Sciences

FAST FACTS

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Positioning Statement

Microsoft Dynamics™ AX for Life Sciences is a customizable, scalable, and global business management platform which, together with a partner or ISV-provided vertical solution, can help life science companies connect with their business partners, optimize business processes, and gain competitive advantages, while helping to simplify the validation processes mandated by the FDA and other regulatory agencies.

Market Definition

The life sciences segment is defined as companies that research and produce pharmaceuticals, nutraceuticals, biotechnology, and medical devices for use in humans

Types of Products

- Pharmaceuticals – generic, brand name, and over-the counter (OTC)
- Medical Devices
- Biotech
- Nutraceuticals

Types of Organizations

- Manufacturers
- Distributors

Commonalities and Opportunity Drivers

- FDA/ICH regulations
- Primary ERP opportunity driver is Part 11 compliance requirements
- There are other business drivers

BDMs

- CXOs – Decision makers are at this level perhaps more often than other industries due to the personal risks of noncompliance
- VP Quality – Quality is a primary component of the compliance strategy and therefore the VP if this department is often involved. cGMPs (FDA current Good Manufacturing Processes) mandate that Quality be a separate department so there is almost always a VP of Quality in the larger companies
- Chief Compliance Officer – may be the CTO or not

Market Opportunity

- Microsoft sees more than 2500 potential customers in the life sciences space, only counting countries where Microsoft Dynamics AX has already been released,
- The barriers to our partners entering the life sciences space are high, due to complex GMP and validation requirements,

- Microsoft can help our partners enter this space by providing a GMP-qualified solution platform, as well as documentation that can help simplify validation,

Solution

Microsoft Dynamics AX for Life Sciences is an integrated business application platform designed for companies in the life sciences industry. The platform has been prepared for validation according to regulations applied by the US Food and Drug Administration (FDA) and other regulatory agencies.

The solution is installed as a standard Microsoft Dynamics AX Service Pack 1 implementation. It provides additional functionality such as electronic signature, and changes the functionality of the underlying Microsoft Dynamics AX 4.0 Service Pack 1 solution, so that it can adhere to the strict system controls required by the FDA and other regulatory agencies. The solution also provides a comprehensive set of qualification documentation.

Together with a partner or ISV-provided vertical solution or “add-on,” Microsoft Dynamics AX for Life Sciences is a customizable, scalable, and global business management solution that helps companies in regulated industries connect with their business partners, optimize business processes and gain competitive advantages, while simplifying FDA validation processes.

The main difference between Microsoft Dynamics AX 4.0 and Microsoft Dynamics AX for Life Sciences is that Microsoft has documented a manufacturing process based on Microsoft Dynamics AX 4.0 that supports Good Manufacturing Process (GMP) requirements. We have added validation-mandated functionality such as electronic signature, which requires tight integration with core Microsoft Dynamics AX technology. Microsoft has also added specific update and change control processes necessary for such an environment.

The following features have been added specifically for Microsoft Dynamics AX for Life Sciences:

- Electronic signature
- Improved BOM control (removes ability of users to edit BOMs after they have been approved)
- Improved production status control
- Improved route control
- Improved traceability of unauthorized login
- Improved feature configuration control

Note that all these modifications to the core functionality of Microsoft Dynamics AX 4.0 are mandated by requirements enforced by the FDA and other regulatory agencies. The changes to the functionality will be manifested in any Microsoft Dynamics AX module in which the functionality appears.

All standard Microsoft Dynamics AX 4.0 modules can be used with Microsoft Dynamics AX for Life Sciences. The specific Microsoft Dynamics AX functionalities that have been modified to help companies comply with GMPs will operate consistently across the entire solution and all installed Microsoft Dynamics AX modules.

Microsoft Dynamics AX for Life Sciences is only a platform. Customers in the life sciences industry will require partner or ISV-developed add-on solutions to obtain the specific functionality they will need to support their operations. Microsoft Certified Partners will continue to provide specific knowledge and support of the very detailed industry requirements.

Definitions

FDA	US Food and Drug Administration. It is the United States governmental agency responsible for the evaluation and approval of medical devices.
GMP	Good Manufacturing Practice (regulation); GMP is a set of regulations requiring that quality, safety, and effectiveness be built into foods, drugs, medical devices, and biological products.
21 CFR Part 11	Title 21 of Code of Federal Regulations Part 11. Regulation issued by FDA regarding use of electronic records and electronic signatures.
Qualification	The process of demonstrating whether an entity is capable of fulfilling specified requirements. Ref.: ISO 8402. Qualification of an IT application includes: <ul style="list-style-type: none"> • Assessment if the specifications are appropriate for the intended use • Verification that the functionalities actually are in accordance with specifications.
Validation	Establishing documented evidence that provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes. Ref.: FDA.
Certification	Certification, conducted by a Microsoft-approved Certification partner, is intended to help ensure that each Microsoft Certified Partner that wants to implement Microsoft Axapta for Life Sciences is properly trained and able to meet the special needs from customers in the regulated industries.

Microsoft Dynamics AX Compliancy Strategy and Product Roadmap

Organizations are required to be more and more cautious of the way they do business and compliancy is becoming a broad need. Some industries require more support of compliancy scenarios: Food & Beverage, Chemicals, Cosmetics, Pharmaceutical, High tech, Professional Services (e.g. legal), Aerospace and Defense, Public Sector, and more.

At the same time we can see a broad need for solution that supports GRC (Governance Risk and Compliancy). Microsoft Dynamics AX will provide a versatile solution that can help comply with more regulations.

This requires enabling “ease-of-compliance” and to deliver a platform that can easily be configured to support compliancy needs through different industries.

From software perspective compliancy is about controlling access and modification of information that are available in the business application. Compliancy is also about implementing ability to set up processes to comply with “internal” policies like in Finance, Quality Management, HR, Payroll, and almost management of all sensitive data.

Microsoft Dynamics AX is committed to be a ‘best in class’ solution for regulated environment and compliancy. Microsoft Dynamics AX is going to extend the reach of the solution to meet other regulations requirements for other industries and horizontal needs.

- Examples of industries that require such compliancy scenarios: Food & Beverage, Chemicals, Cosmetics, Pharmaceutical, High tech, Professional Services (e.g. legal), Aerospace and Defense, Public Sector.

Microsoft will extend the capabilities of Microsoft Dynamics AX:

- Expand the reach of Control parameters that are currently limited to FDA 21 CFR Part 11
- Expand the reach of Electronic Signature solution to support more scenarios and include encryption and use of PKI to enable non-repudiation capability
- Simplify the documentation process for certification

Microsoft will introduce a new solution that will help with different compliancy scenarios by providing Digital Signature for securing data / business processes management and using Sure Step tools for documenting those processes.

Going forward Microsoft will extend capabilities and supported scenarios, as a result **Microsoft Dynamics AX 4.0 SP1 is the last version that is going to be validated.**

- For Microsoft Dynamics AX 4.0
 - Microsoft Dynamics AX 4.0 SP1 for Life Sciences GA: February, 1st 2008.
- For Microsoft Dynamics AX 2009 (subject to change):
 - Introducing Digital Signature, a pervasive solution, that can support various regulated environments and horizontal needs.
 - Digital Signature will provide both Electronic Signature and Digital Signature capabilities including non repudiation capabilities.
 - Test documentation which is part of the current validation is going to be made available to customers and partners. Sure Step Task Recorder can help document customized business processes to be certified.
 - Discontinuation of the Microsoft Dynamics AX for Life Science SKU (the validation documentation SKU). The e-signature SKU will remain available to support existing customers and will be discontinued with next release. New customers are recommended to use the Digital Signature when available.
- Beyond Microsoft Dynamics AX 2009
 - Expand compliancy scenarios and capabilities.
 - Digital Signature (including simple electronic signature scenario) to support various regulated environments and expand its capabilities (e.g. Enterprise Portal, integration with Workflow).

Note that no vendor can guarantee the successful validation of any given Life Sciences implementation. Compliance with regulatory agency requirements depends in a large part on the processes or standard operating procedures within the customer organization. Microsoft Dynamics AX for Life Sciences, along with a partner or ISV-provided vertical solution, can support a customer's compliance strategy but the ultimate responsibility continues to belong to the customer.

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