

# Compliance for the pharmaceutical industry

How to comply with regulations and  
achieve maximum quality.



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## 01 | YAVEON ProBatch for the pharmaceutical industry



Pharmaceutical companies face stringent regulations on a daily basis. The gathering of ever more information, meeting rigorous quality demands, and strict process monitoring is ever more time-consuming. Not to forget change controls, computer system validation, and much more. To summarize, they face numerous chal-

lenges. Can an ERP solution help with this? Yes. At least, if it's the right one. The most important criterium is that it must meet the requirements of your industry.

## 02 | The Base: Microsoft Dynamics 365 Business Central

### Made for SMBs

Microsoft Dynamics 365 Business Central is not just any ERP system, but one that is tailored to the needs of small to medium-sized businesses. In other words, you work with a solution that suits you, and that isn't complicated by unnecessary functions and fields.

### Navigation: intuitive

Almost everyone knows Excel, Word, and PowerPoint, and understands, at least for the key functions, how to use these programs. So why use an ERP system that is completely different? Microsoft Dynamics 365 Business Central adheres to the typical Microsoft design. Which means the navigation and usage of the solution are intuitive.

### Use it - immediately and from anywhere

No installation is required; you can start immediately – because YAVEON ProBatch works via a webclient. As the system is also available as an app on all mobile devices, you can use the functions at your desk, on the train, or even on a bench in the park.

### Shut down stand-alone solutions

Microsoft Dynamics 365 Business Central is fully integrated into your Microsoft 365 package. This means that you no longer need stand-alone programs that run parallel to each other. Instead, you get a single solution with a uniform structure – all in one system. These include, for example, the integration of Microsoft Power BI and the Dynamics 365 sales solution.

### A secure investment

Microsoft is tried and tested: More than 3.3 million users rely on the Microsoft ERP system – and have done so for many years. Business Central is the latest version of the solution, which was launched over 30 years ago. It's undeniable: With Microsoft, you're banking on experience and longevity at the same time. That's a safe investment.

### Modifications? Easily done

Whether adding more employees, restructuring, or just new requirements, companies change, and with them, your expectations of an ERP sys-

tem. Don't worry; you don't have to start new ERP projects on a regular basis to meet these needs. Microsoft Dynamics 365 Business Central changes with you, making the entire system scalable. If you need more users, just add them in. If you need more features, simply add as an app – future updates are, of course, still possible.

Ok, that makes sense. The next question is: If Microsoft Dynamics 365 Business Central is so perfect, why do you need an additional industry solution, and one which takes time and money to set up?



An insight into the system: Microsoft Dynamics 365 Business Central

## 03 | Facts on the table: Do you really need an industry solution as a pharmaceutical company?

To be honest, not for everything. There are many processes that you can map with Microsoft Dynamics 365 Business Central.

But to actually and sustainably facilitate your everyday work, you need additional functions that are specially adapted to the pharmaceutical industry. Providing you with a solution adapted to your company, not one to which your company has to adapt.

An industry solution is, therefore, more than just a possible add-on. It is an ERP extension that brings you an unbeatable argument: better results with less work.

### The essential functions covered by the YAVEON ProBatch industry solution for the pharmaceutical sector:

- ✓ Key industry functionalities are included.
- ✓ Meets regulations and requirements. If these change, the solution is ready for necessary adjustments.
- ✓ You use a role-based interface. Every employee sees the functions and data that are necessary for their area.

### An industry solution also means a specialized industry partner

Features are one thing; consulting is another. A good ERP solution for the pharmaceutical industry comes from a vendor that is as at home in your industry as you are. Because only then does the vendor know what really matters. And this brings advantages. You communicate on an equal footing, your concerns are met with understanding, and you benefit from the experience of your software partner.

**Can YAVEON do all this?** Numerous projects, many audits, and consultants who draw on many years of knowledge in the pharmaceutical industry. Our employees know their way around your industry and how to avoid stumbling blocks. This knowledge comes from three sources: Professional training and development, regular department meetings, and project experience. Because changes are often required, especially in a regulated environment, it is essential to be up-to-date. To carry out an industry project successfully, you need a partner who knows their way around. This builds trust and a sense of community because consulting is only effective if it provides real answers. Or would you have your building rewired by a painter?

## 04 | The most important reasons why ProBatch is just right for you:

### 1 Work reliably and transparently: computer system validation (CSV)

CSV: indispensable in the regulated environment and yet extremely complicated. YAVEON makes this easier – because our solutions are specially developed for this purpose. The process is simplified by extensive documentation and our consulting expertise. This reduces your workload and ensures a smooth validation process.

### 2 Meet regulations: fulfill compliance requirements

The be-all and end-all in the pharmaceutical industry: Regulations and the requirement to meet them – and of course, that goes for software too. YAVEON ProBatch meets all the required standards, and the dedicated compliance app offers everything you need when it comes to complying with all regulations.

### 3 Save time, money, and paper: electronic signature

Save valuable resources with electronic signatures, based on the dual control principle (one or two person rule). Because the signature is completed faster, and you don't need paper or postage stamps. The electronic signature also offers security in all relevant processes - an unbeatable argument.

### 4 Keep all batches under control: batch management

Do you want or need to keep track of which lot was used when, under which conditions, and for which process? YAVEON ProBatch combines a variable set of rules and freely definable batch statuses that can be used to standardize your processes.

### 5 Highest standards: quality inspection

When it comes to quality, you don't compromise – and neither does YAVEON ProBatch. From the incoming raw materials goods inspection to the inspection of semi-finished or finished goods, and the monitoring of cleanrooms or equipment – the solution digitizes your quality management. The QM module also offers the possibility to combine information in one system and manage it with the batch data.

### 6 Support the process industry: everything for SMBs in the life sciences

ProBatch is not just any software. It is a tailor-made ERP solution for SMBs in the life sciences industry. It includes all the important options that make your day-to-day work easier and more secure.

## 05 | The YAVEON ProBatch modules are available as individual apps. Why is that?



### All possibilities - with low complexity

You have decided to implement an ERP system – but do you really need all the features? Not necessarily. Because YAVEON lets you choose individual apps, you get exactly the features you need for your work.



### Scalable

Demands change – just like your ERP features. If required, simply add further apps and take advantage of even more possibilities with YAVEON ProBatch.



### In stages instead of all at once

Adding features gradually doesn't only mean you benefit from more options when you need them. As you extend YAVEON ProBatch as needed, your users increase their familiarity with the solution, and it becomes an integral part of their everyday work.



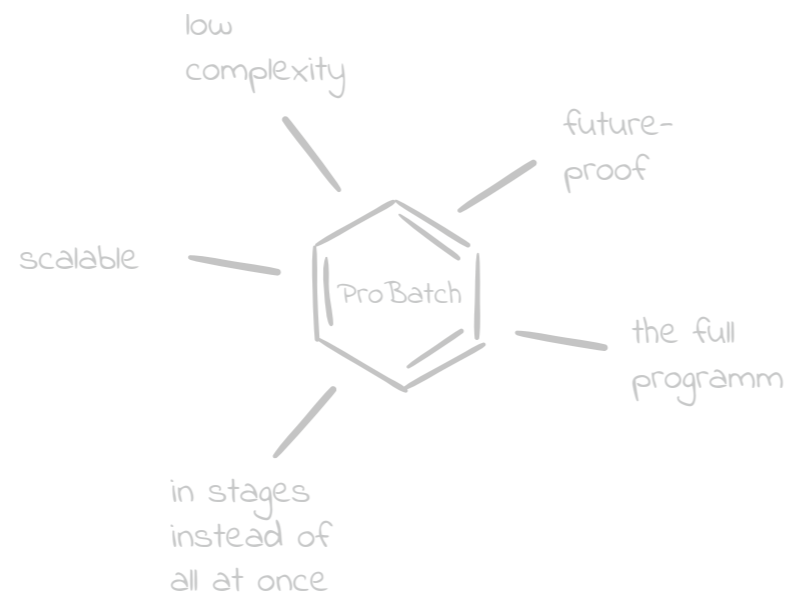
### The full program

Many apps, many possibilities. Yes – and if you prefer, all at once. You still benefit from the advantages of a modular implementation, but it's all done in a shorter project timeframe.



### Future-proof

The software world has arrived in the cloud. That's why Business Central, ProBatch and our apps are of course cloud-ready and are kept up to date with regular updates.



## 06 | YAVEON ProBatch – Top 10 modules for the pharmaceutical industry



### Advanced Inventory Summary

Inventory information made easy – never lose track with us!



### Trade

Find the negotiated price - not just the lowest.



### Quality Assurance

Check your quality - continually, automatically and reliably.



### Lot Management

Manage your batches - systematically and with the push of a button.

Process	Line	Item	Serial No.	Lot No.	Item No.	Item Description	Location Code	Quantity	Remaining Quantity
Finished Production Order	Output	FA000001		LOT000139	C1000001	VAW/COLOUR blue	MUNICH	100	100
Finished Production Order Consumption		FA000001		LOT000101	C1100001	Calcium carbonate filler	MUNICH	-15	0
				LOT000101	C1100001	Calcium carbonate filler	MUNICH	3,500	3,485
							MUNICH	-60	0
							MUNICH	2,650	2,590
							MUNICH	-25	0
							MUNICH	1,600	1,575
							MUNICH	1,200	1,200
							COLOGNE	15,000	15,000
							BERLIN	5,000	5,000

ProBatch 365 Lot Management





### Compliance

Meet the high demands of a regulated environment and comply with statutory regulations and standards.



### Warehouse

Simply automatic - automatically simple: Store and move your stock more efficiently.



### Manufacturing

YAVEON ProBatch 365 Manufacturing supports planning and processing of lot managed manufacturing.

**Load Carrier List**

No. ↑	Load Carrier Type	Location Code	Bin Code	Item No.	Unit of Measure Code	Lot No.	Expiration Date	Date of Entry	Height
PAL000246	EURO	MUNICH	RM-02-02-02	E1200005	PCS	LOT000004	5/25/2027	9/8/2020	0
PAL000247	EURO	MUNICH	RM-02-02-03	E1200005	PCS	LOT000004	5/25/2027	9/8/2020	0
PAL000248	EURO	MUNICH	RM-02-02-03	E1200005	PCS	LOT000004	5/25/2027	9/8/2020	0
PAL000250	EURO	MUNICH	REC-01	E1200002	KG	LOT000024	1/1/2025	9/15/2020	0
PAL000251	EURO	MUNICH	RM-03-03-02	E1200002	KG	LOT000023	1/1/2022	9/15/2020	0
PAL000252	EURO	COLOGNE	S-01-0001	C1000001	L	LOT000090	11/4/2021	11/4/2020	0
PAL000253	EURO	COLOGNE	S-01-0001	C1000001	L	LOT000090	11/4/2021	11/4/2020	0
PAL000254	EURO	COLOGNE	S-01-0001	C1000002	L	LOT000089	11/4/2021	11/4/2020	0
PAL000255	EURO	COLOGNE	S-01-0001	C1000002	L	LOT000089	11/4/2021	11/4/2020	0
PAL000256	EURO	MUNICH	REC-01	E1200000	KG	LOT000094	1/1/2024	11/4/2020	0
PAL000257	EURO	MUNICH	REC-01	E1200000	KG	LOT000094	1/1/2024	11/4/2020	0
PAL000258	EURO	MUNICH	REC-01	E1200001	KG	LOT000095		11/4/2020	0
PAL000259	EURO	MUNICH	REC-01	E1200001	KG	LOT000098		11/16/2020	0
PAL000260	EURO	MUNICH	PR-03	10047	PCS	LOT-0084	4/16/2031	4/16/2021	0
PAL000261	EURO	MUNICH	PR-03	10047	PCS	LOT-0084	4/16/2031	4/16/2021	0

ProBatch 365 warehouse



**Delivery Rating**

General  
 Source Filter: [ ] Rating Type: Purchase  
 Class Filter: [ ] Valid from filter: [ ]  
 Criterion Filter: [ ] Valid to filter: [ ]

Manage Copy Soft Criterion Copy aut. Criterion Open in Excel Actions Fewer options

Rating Type	Source No.	No.	Description	Class	Class Description	Weighting
Purchase	K00040	01_100	Quantity Reliability	01	Shipping	1
Purchase	K00040	03_100	Partial Deliveries	01	Shipping	1
Purchase	K00040	04_100	Quality	01	Shipping	1
Purchase	K00040	PRICE	Price	02	Pricing	1
Purchase	K00040	SERVICE	Service	03	Service	1
Purchase	K00040	COMMUNICA...	Communication	03	Service	1

**VENDOR RATING**  
Period: 01.01.20..31.12.21

Shipping (Weighting 2) Scored points: 83

Description	Weighting	Number of Points
Quantity Reliability	2	96
Deadline Reliability	1	68
Partial Deliveries	1	90
Quality	1	84

Pricing (Weighting 1) Scored points: 80

Description	Weighting	Number of Points
Price	1	80

Service (Weighting 1) Scored points: 90

Description	Weighting	Number of Points
Communication	1	90
Service	1	90

Scored points: 84 Rating C/Vendor

ProBatch 365 Delivery Rating



### Delivery Rating

Grading made easy: Evaluate the quality of your suppliers and your own deliveries.



### Research & Development

Integrated R&D: Development of new products and recipes, integrated into your business processes.



### Costing

Calculate Item Price and Costs - Simply and Easily.



more apps  
/

In addition to our top 10, you can access the following apps **if required**:

- ✓ Hazardous Substances Management
- ✓ Plant Data Acquisition
- ✓ Sales and Purchase
- ✓ Incident Management
- ✓ Scanning
- ✓ Visual Planning
- ✓ Joint Production
- ✓ Scale

**But there's more:** we are constantly working on even more options so that you can automate your processes more comprehensively. Whether additional functions or completely new apps - our range is constantly growing. You can find all the information you need at any time on our website or on AppSource.

[Go to website](#)

[Go to AppSource](#)

## 07 | YAVEON ProBatch as SaaS in the cloud

Welcome to the age of Software as a Service! Worried about data leaks and outages? No need. Because all our systems meet the important security standards. Flexibility, future-proofing and the ability to grow with you: solutions in the public cloud are the ideal basis for you to use your ERP in the long term and remain successful in the long term.

### The most important facts about the public cloud at a glance:

- ✓ Public cloud on Microsoft Server „Azure“
- ✓ Software as a Service (SaaS): Infrastructure is provided in full, maintenance work, back-ups and further developments are outsourced. IT departments gain time for their actual tasks.
- ✓ Enables scalability and provides flexibility.
- ✓ Payment possible as a monthly or annual subscription
- ✓ Distribution of total costs over several years
- ✓ Regular localized compliance, governance and security updates
- ✓ Prevents data loss.
- ✓ Failure and data security are ensured.
- ✓ System is always „up-to-date“ thanks to automated updates.
- ✓ No more manual updates and/or new projects necessary.



ProBatch as  
Software as a Service

## 08 | How does a ProBatch project work?

As you spend a lot of time with your consultants during the project phase, it is vital that you can work well together. For this reason, you will get to know your key consultant and our proven project methodology YAVEON ProCedures before the project begins, because who wants to buy a pig in a poke?



### Presentation system and comparison with requirements

The first step is to get to know the system, and compare requirements with capabilities.



### Get to know the project team

The chemistry must be right. That's why you should get to know your YAVEON consultant right at the start.



### Project launch

Ready, steady, go: Together, we start full steam ahead and begin the joint ERP project.



### Implementation

Now it's time to get down to business: The YAVEON ProBatch implementation is the core of your project.



### Tests

Testing, testing, testing. Processes and functions are checked several times to ensure that everything runs smoothly.



### Go-live

The big day has come: Together, we implement the real start of YAVEON ProBatch.



### Service and support

Once the system is in use, the support phase begins. If you have any questions, YAVEON support is there for you.

Different company sizes, different requirements: Every ERP project is different. But they all have one thing in common: **they involve the full expertise of our team:**

- ✓ Experience from over 550 customer projects
- ✓ Maximum know-how in all aspects of computer system validation
- ✓ Expert in the process and batch processing industry
- ✓ Large project team in Germany and Switzerland
- ✓ Solution in use worldwide via extensive partner network



## 09 | That's what our customers say

The best proof of successful projects is satisfied customers. In our references, we regularly give companies the opportunity to speak honestly and realistically about their software project with

us. We have put together a few quotes for you. You can find the full reports and even more customer testimonials on our reference page.

### Our references

Petra Duchrau



It was clear from the first second that the consultants at YAVEON were knowledgeable about validation. Right from the start, the cooperation was excellent, and we were on the same page.

Shami Kaur Bala



The YAVEON consultation was and is always very detailed. Our concerns are dealt with quickly, which is particularly important for us.

Gerry Wallner and  
Andreas Lübke



The YAVEON team knows HELM inside out, and that is incredibly valuable.

## 10 | What's next?

Now you know the most important information about YAVEON ProBatch and why the solution is ideally suited for the pharmaceutical industry. Would you like to make personal contact, get

answers to your questions, or even arrange a short demo of the system, and take advantage of its many benefits?

### Contact us now



An insight into the system: YAVEON ProBatch for the pharmaceutical industry

## Contact

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