

Arctive illuminate the GxP Cloud Computing Environment.





# Digitalization in the fast lane

Arctive.PHARMA accompanies the life science and pharmaceutical industry!

The specialists in medicine, pharmacy and pharmaceutical chemistry are currently facing a multitude of fundamental challenges. Secure data quality and integrity, time-accurate and correct traceability throughout the entire life cycle of a product, increasing GxP requirements as well as the guidelines and regulations of Swissmedic are THE buzzwords.

We automate your value chain. Your challenges are our motivation:

- Complex business processes and increasing networking...
   We automate processes across company boundaries.
- Increasing speed of innovation cycles...
   We provide strategic support and automation to accelerate release processes to innovations.
- Increasing operational overhead...
   We reduce operational overhead and relieve clerical assistant through automation and artificial intelligence.

Automation increases security while improving the satisfaction of their employees and customers.

#### Adrian Alioski / Product Owner Custom Applications, Baloise

"Even 1.5 years after go-live, the jointly developed solution for one of our largest pharmaceutical customers still inspires! Arctive supports us in the operation and further development of the solution and convinces as a sustainable partner!"



#### COMPLIANT | SECURE | EFFICIENT

Arctive AG is a Swiss IT services company. As an IT expert, we have specialized in cloud-based solutions for the demanding segments of Pharma, Energy, and Insurance. All three industries have one thing in common – the regulatory requirements and complexity are massive. We love these challenges.

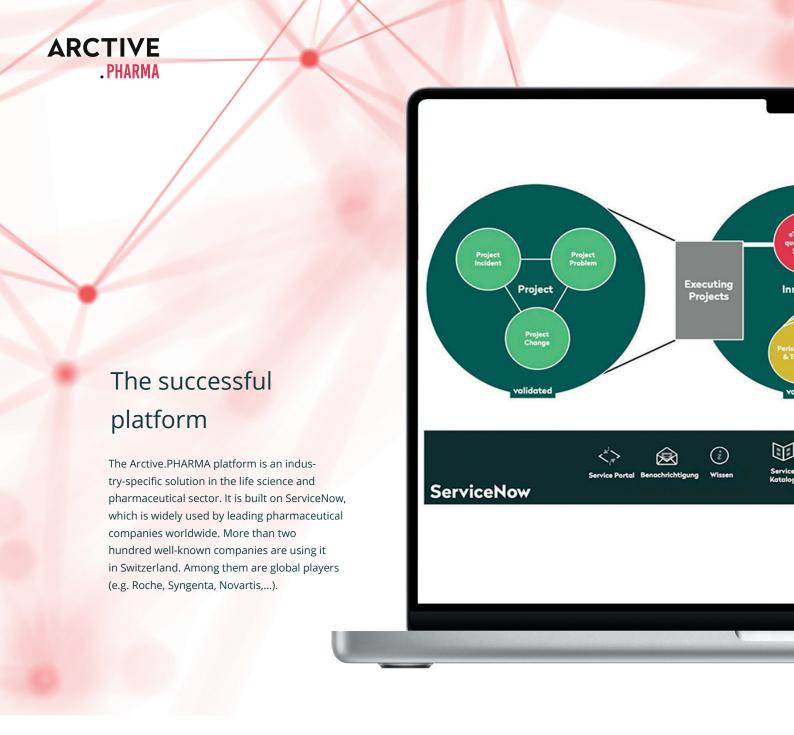
**Our many projects have made us the leading experts in industry solutions.** As a result, our experts have comprehensive, specialized knowledge, from which our customers additionally benefit through better understanding and faster implementation.

In the life science and pharmaceutical sector, we are remarkably familiar with the core systems as well as internal processes and focus on compatible solutions and workflows that are fully integrated into their IT landscape. For example, we develop end-to-end, automated control mechanisms for Corrective and Preventive Action (CAPA) and offer process automation to ensure the GMP requirements. Our Arctive. PHARMA experts use the ServiceNow technology as a central nervous system and customize the solution to perfectly fit the needs of your company.

ServiceNow is an incredible platform for digitizing business processes: integrative, unified, flexible and extremely robust. Today, it offers machine learning, artificial intelligence and chatbots, predictive analytics, and natural language processing, in addition to workflows.

ServiceNow technology is based on workflow-driven automation of processes. The ServiceNow platform itself is the central nervous system that controls, measures, and automates all of a company's workflows and processes across departments.

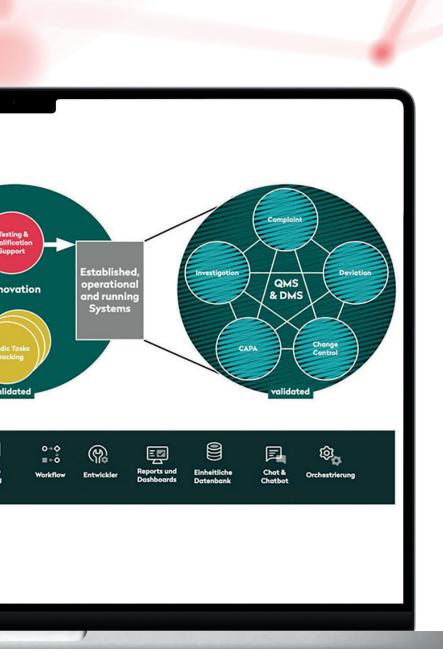
This cross-departmental mindset leads to higher customer satisfaction, better reputation, leaner and more efficient processes, and thus higher customer and employee satisfaction, increasing revenues, lower costs and more profit.



Enable easier updates in IT systems by reducing paper and expending CSV and periodic

Enable the agility of modern cloud platforms and update cycles while maintaining validated

Support project quality in an effortlessly with turn-key processes for introducing new IT solutions





# Cyber security is a top priority.

#### Arctive.PHARMA is secure.

Arctive.PHARMA protects against any form of attack. It allows working during an upgrade.

#### www.servicenow.com/trust

The ServiceNow platform, the technology and secure and privacy-compliant operations are rigorously audited. It is on a regular basis by independent third parties and government agencies to ensure they meet all relevant global and regional standards.



Running projects for IT systems which need to validate, without CSV in mind from the start, makes validation harder and slows down these projects. Comprehensive project support tools mitigate that. Such tools help you use modern cloud platforms with their agile updates while ensuring constant re-validation and execution/tracking of periodic tasks.



Paper-based processes can bog down validation effort as proof will regularly require manual screenshotting of individual steps in qualifications as well as manual signatures.

Arctive.PHARMA replaces this with comprehensive e-Testing including detailed screenshots and enables digital signatures throughout the process.



Supporting the life cycle of validated IT systems and the connected documentation to retain a compliant state can be either difficult or simple. Use our turn-key solution for ensuring compliance, or seamlessly integrate your own QMS and DMS.



# Highlights

### Ready-to-use

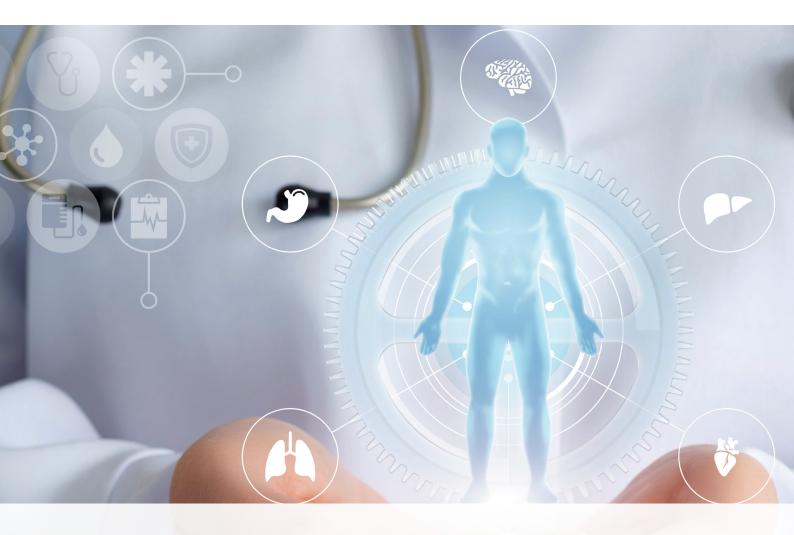


Arctive.PHARMA comes with best-practice, turn-key workflows, and solutions as a starting point. They can be customized to fit any individual needs and requirements.

### Swiss quality



Arctive.PHARMA is a Swiss solution. All processes are clearly defined, consistent and documented. Critical process steps are marked, all processes are stringently validated and under change control.



#### **GAMP**



Arctive.PHARMA is aligned to Good Automated Manufacturing Practice (GAMP) Levels and can be tailored to suit your SOPs.

#### Periodic task



Arctive.PHARMA helps Periodic Task Tracking and ensures execution of internal controls including proof of execution and results, both of which can be reported on.

# Hand-over processes

Arctive.PHARMA facilitates efficient hand-over from project to operations, mitigating risks and reducing time needed for testing and qualification of IT systems.

#### Validation built-in



Arctive.PHARMA has Validation and Revalidation built-into the solution but separate from other platform processes. No dependencies and blockages during system updates. Being securely validated in an agile cloud environment is possible.

### Integrated



Arctive.PHARMA is built to be integrated easily with all types of pharma IT systems like EDMS, QMS, LMS or other pharma solutions. ServiceNow supports all modern integration technologies/Web- Services and is quickly integrated with any type of IT system (LDAP, AD, SAP, or any other solution).

#### Full audit trail



ServiceNow has revision-safe archiving and a full audit trail (everything is logged) ensuring constant data integrity.

# E-Signature



Arctive.PHARMA has a robust, integrated user management and supports digital, electronic signatures using e.g. DocuSign.

#### Workflows



Arctive.PHARMA is workflow-driven and guides users with flexible approval processes. This allows new employees to reach productivity rapidly. User and process errors significantly reduced.



# The Team Solution

# System / Service Owners

Arctive.PHARMA allows them to find all relevant documents and validation information concerning their systems in one easily usable and searchable interface. Periodic tasks can be tracked in the same system and are interlinked. The system helps them plan, operate and modify information systems while ensuring the systems are validated. Results are audited and reporting on task status is straightforward.



#### Quality Heads

They know the current state of quality for relevant IT systems and have control over setting policies and procedures. Simple unified dashboards, fully searchable information and consolidated reports of identified issues are at their disposal. Concurrently all information is safely synched with the DMS. Arctive.PHARMA also provides an oversight of tasks remaining and active tracking.

#### **Process Owner**

With Arctive.PHARMA Process Owners can design, develop, and manage processes on IT systems. They can be sure the processes are properly validated to ensure compliance. They also find all relevant documents and validation information concerning their processes in one easily usable and searchable interface. The comprehensive history allows them to judge the impact on process risk.





#### **Compliance Officer**

They can ensure that IT projects for validated systems are run in a compliantly and adhere to the relevant regulations and standards. Retrieving proof for this is easy, and identification of areas of improvement or lacking progress is supported by comprehensive, role-specific dashboarding.

#### **CSV Experts**

They use their expertise to configure and tune the e-Testing and qualification capabilities. This enables repetitive, timely and more automated validation and re-validation of IT systems. The ability to execute these automations (documented and digitally signed results) helps speeding up the process.



### IT Project / Validation Manager

They are able to prepare validation documents and ensure, during the course of the project, that any issues and changes are well documented and can be easily found and referenced. Hand-off to DMS systems is managed automatically.

#### **Quality Manager**

They verify that validation has been conducted correctly and assess deviations between plan and final report. Having the ability to retrieve all relevant documentation (securely audited, digitally signed and in sync with DMS systems) in one place expedites this process and ensures quality. The ability to easily perform a full-text search on all attached documents supports this work.



# The Arctive 3\*3 Approach

# The life science and pharmaceutical industry is currently facing fundamental challenges.

Regulatory requirements are increasing, while at the same time the operation of infrastructure in compliance with regulations is becoming more expensive. The digitalization and networking of the economy is leading to more interfaces between different players. The digital transformation must be designed quickly and efficiently and orchestrated centrally. Pharmaceutical industry players must ensure that their solutions work the way they want them to. And not after months of project development, but immediately, before important decisions are made.

Arctive.PHARMA is happy to provide this proof with the 3\*3 approach. In only three hours we develop together with you live a demonstrative solution of your challenge or business idea. You will not only see the result, but also experience first-hand how Arctive experts work with ServiceNow technology, how adjustments are made quickly and easily. You will get a first impression and if you are convinced, we will prove the chosen solution in a proof-of-concept which we can deliver in only three days at a fixed price.

The proof-of-concept is tried, evaluated, and put through its paces by you and necessary subject matter experts and users. We can also import and use parts of your own data in a PoC so that you can get a realistic picture.

If you then decide to implement the solution, we will develop the PoC into a production-ready solution that you can go live within 3 months. This includes technical implementation with documentation and professional access security, data protection and integration with your core systems. We also ensure the training of your employees, go-live support, and our availability in the hyper care phase.

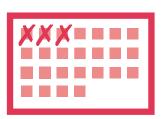
#### Adrian Alioski / Product Owner Customer Applikations, Baloise

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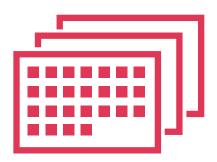
# 3 hours

We build a live demo solution specific to one of your real use cases.



# 3 days

We prove the feasibility of your solution and build your prototype in three days.



# 3 months

We build your production-ready solution in three months.



# 100% Arctive



#### **Arctive Advice**

We advise you and set you on the path to digital success. We support you in your digital transformation challenges. We analyze your processes, uncover potentials and inefficiencies in existing processes, enable synergies and thus prepare your process landscape and workflows for automation.



# **Arctive Build**

**We build your solution.** Our focus is the development of individual business applications and portals based on ServiceNow technology. We move on the App Engine, the Customer Service, IT Operations as well as the IT Service Management of ServiceNow.



## **Arctive Care**

We accompany you also after the go-live because we maintain what we have created. Since we often have mission-critical applications, we also provide the appropriate support for our solutions. In case of release changes or new system requirements, you can easily rely on our expertise and support.







#### For specific Challenges.... specific Solutions

Our apps integrate seamlessly with your solution, saving development time and ensuring you're on the safe side during release changes.

# Deployment Guide 🔇



Mit der Deployment Guide® App ist eine benutzerfreundliche Schnittstelle für die Dokumentation und Überprüfung von Implementierungen sichergestellt. Der Guide ermöglicht, Dokumente zu verfolgen und zu verwalten, die Performance zu überprüfen und die Versionshinweise zu kontrollieren.

## NoCode PDF



Mit der NoCode PDF® App lassen sich gestylte und gebrandete PDF generieren ohne diese zuvor aufwändig Codieren zu müssen. Briefe, Reports, Listen und Tabellen lassen sich einfach konfiguartiv in Templates einfüllen und als Ergebnis erhalten sie CI-konforme Dokumente für ihre interne und externe Kommunikation.

## **Swiss Tool**



Mit der Swiss Tool® App verkürzen sich die Entwicklungszeiten für Projekte mit Portalen deutlich. Sie profitieren von Vorteilen wie stark verbesserten Formularen, verbessertem Attachment Handling, attraktiven Process Flows, Related Lists sowie u.a. einer Klassi-



# Our values and principles

At Arctive, we help you "vitalize" your business processes. Your customers and employees get fast and intuitive tools that increase and improve quality, compliance, efficiency, and productivity.

During the transformation, we clearly **focus on your needs**. Your employees, business partners and customers receive **solutions** that are a **pleasure** to use and that you no longer want to do without.

We like to take the term service literally. For us, it consists of two parts: **Serving and performing**. With everything we do, we serve you, our customers, and their goals. For us, service means that we proactively use our expertise, think along with you, question and really go the extra mile for you.

#### We go the extra mile for you.

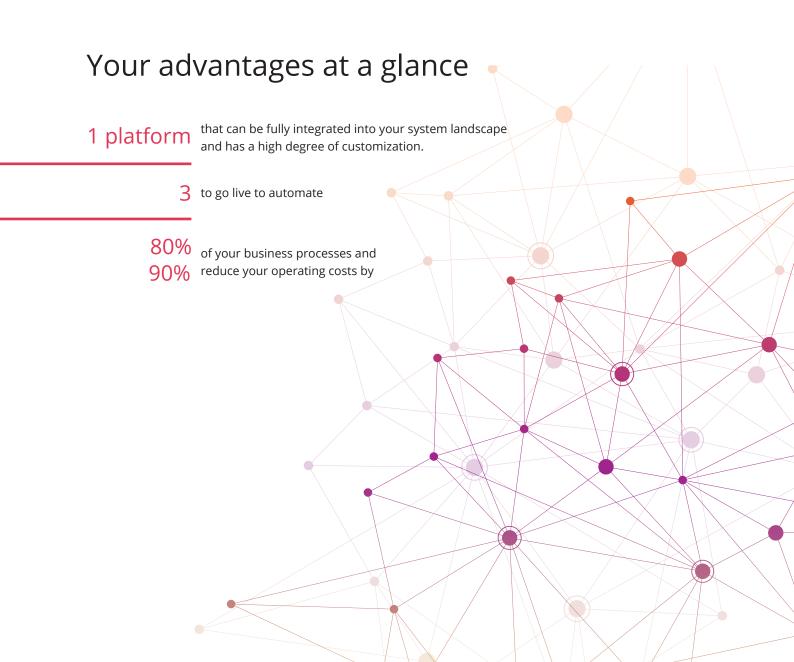
Arctive.PHARMA is there when things get difficult and complex. Real experts, Swiss quality, on site. We help the life science and pharmaceutical industry to sustainably improve their business with their IT. Together with our customers, we take responsibility for the implementation of digital solutions and processes.

We build the bridge to the IT system world, create synergies, resolve the complexities for our customers – we enable simplicity and efficiency.



Patrik Bichsel, Head of Arctive.PHARMA

"Anything that has an interface can be robustly and easily connected bidirectionally."



#### Contact us now!



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