



Jacques

Principal Consultant Lifescience

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info@antaes.ch



ANTAES

ADVICE OFFER

Pharma 4.0



ANTAES

Headquarter - Geneva Business Center
2, Avenue des Morgines CH - 1213 Petit-Lancy



Partnership for excellence

BUSINESS CONTEXT —

Digitalization is today at the heart of any company strategy, however shop floor digital transformation in the pharmaceutical industry is in its infancy.

The traceability and data integrity requirement specific to pharmaceutical production poses particular challenges to realize the benefits of digital transformation: efficiency and agility.



HOW CAN WE HELP YOU? —

You manage an innovative production project in pharmaceutical or medical device environment, we can assist you in the scoping and management of your project. You want to improve the efficiency of your quality management approach, we are at the forefront of innovative quality management.

You want to digitalize your shop floor, better integrate production data with your enterprise system, improve data integrity etc..., we have implemented and validated numerous systems across the different functions of a pharmaceutical factory.

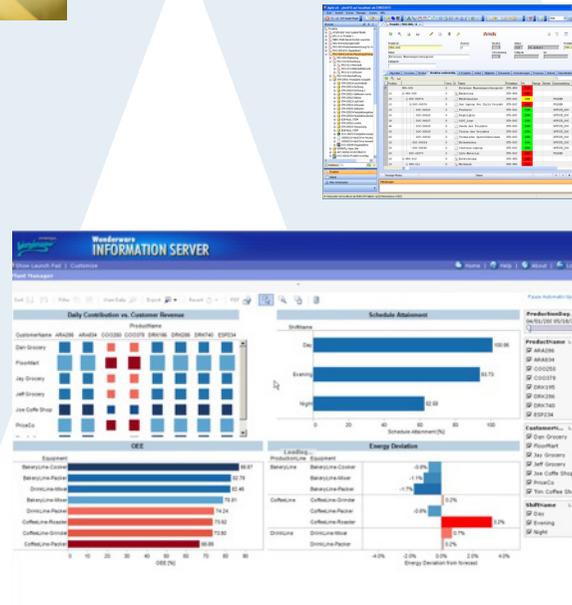
PARTNERING WITH ANTAES —

Antaes is supporting its customers through their digital transformation since its foundation. Via its structure mixing business consulting, industrial and IT expertise, Antaes is a partner of choice to support your transformation projects.

Our approach is based on holistic people centric thinking that encompasses the following:

- **Evolution of the quality management approach from a task centric to a lifecycle and capabilities point of view to improve agility**
- **Evolution of qualification and CSV practices through the deployment of ASTM E2500 for equipment qualification and differentiated approach for enterprise, control and analytical computerized systems**
- **Science based risk management for process validation**
- **Digitalization of the batch release process through the use of integrated computerized system like LIMS, SDMS, MES and Quality Management solutions**
- **Transformation of production and support maintenance practices to an integrated service model**
- **A strict respect of GMP predicate rules through careful review of critical decisions**

ILLUSTRATION



BUSINESS IMPACT OF DIGITALIZATION —

Digitalization of pharmaceutical production will lead to better management of critical quality product attributes and improved controls of critical process parameters thus will lead to significant reduction in waste due to quality deviation.

Realizing the benefits of associated digitalization will require that the different functions (Supply Chain, Production, QA, Engineering and IT) operate using new paradigms and new systems. This represents a significant challenge for an environment traditionally conservative.

ANTAES added value

Antaes has a practical experience in implementing those practices in different industries including pharmaceutical manufacturing - We have a successful track record in delivering small to mid-size pharmaceutical production facilities that have been successfully audited at start up - Our team is composed of experts in matters related to "GMP for the 21st century" as set forth by US Food and Drug Administration - We follow an "Ockham Razor" principle in our decision process to ensure the best fit between product and process constraints

