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## **Sap Validation And Gmp Compliance**

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This ECA course will provide comprehensive knowledge about how to validate SAP S/4HANA for new SAP customers as well as for installed base customers who are planning a system conversion. Expect two days full of shared best practices for the validation of SAP S/4HANA considering recent regulatory requirements like EU GMP Guide Annex 11,

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GAMP 5 and 21 CFR  
Part 11.

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10/11 November 2020.

Course No 18442. ...

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## **SAP - Validation and GMP Compliance**

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(Concept Heidelberg

Seminar) SAP S/4HANA

has been launched in

2015 as the new

intelligent ERP system.

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The software is available as cloud edition and as onprem edition. SAP S/4HANA is being called the biggest update to its ERP system in over two decades. Together with the move to in-memory database SAP HANA a new user interface (SAP Fiori) was introduced.

**Seminar: Validation  
& GMP Compliance |  
DHC Consulting**

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Using SAP Solution  
Manager 7.2 as a  
Validation platform  
(incl. live demo) 0: 38:  
12667: Managing an  
European SAP program  
in a validated  
environment (Olympus  
Surgical Technologies  
Europe) 0: 43: 12668:  
Intelligent ERP:  
Artificial Intelligence /  
Machine Learning and  
GxP Compliance: 0: 27:  
12669: SAP Audit Trail  
in SAP S/4HANA: 0: 35:  
13705

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**ECA - SAP -  
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As the system is used for GMP critical operations (e.g. inventory, master data management, batch release) validation is a must and a critical element of the SAP implementation. Controlled operations, including Change Control will ensure the

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validated state is maintained.

## **SAP - Validation and GMP Compliance**

If your company following to GMP principles usually a lot of SAP-systems in this company (SAP ERP QM/SD/MM/PP and PP/DS modules, SAP TM, SAP EWM, SAP ATTP and so on) are GMP-critical. This fact affects the work of all SAP Consultants in the

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company, including

SAP BASIS

Administrator too.

**SAP BASIS and GMP.  
Step-by-Step guide  
for CR | SAP Blogs**

SAP Validation

Environment For

Pharmaceutical

Companies -

Introduction And Basic

Concepts. ... GxP: The

term GxP means GMP

(Good Manufacturing

Practices) ,where 'x'

includes. GCP (Good

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Compliance  
(Clinical Practices) GLP  
(Good Laboratory  
Practices) GDP (Good  
Distribution Practices)

**SAP Validation  
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Pharmaceutical  
Companies ...**

Computer systems  
where-ever SAP is  
installed, needs to  
Validated for  
compliance with GMP  
as under the USFDA  
21CFR parts 11, 210,  
211. Systems involved

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Validation And

in. Data from SAP  
which is required to be  
made available for  
agency inspection;  
Those which are used  
for submitting  
electronic records to  
agency

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Since 1996 we have  
been supporting  
companies in the life  
sciences industry  
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worldwide as industry experts in the implementation and further development of their SAP systems. Thanks to our expertise in the areas of business processes, SAP and IT compliance, we are now the leading consulting firm in the German-speaking world for the validation of SAP systems.

**SAP S/4HANA  
Validation | EN - DHC**

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S/4HANA has been

launched in 2015 as

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edition and as on-prem

edition. SAP S/4HANA

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ERP system in over two

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COMPLIANCE AND

VALIDATION Our firm

has been offering

consulting services in

the life sciences and

working in the field of

IT compliance since

1996. Our first clients

were SAP customers

from the

pharmaceuticals

industry, who needed

to validate their

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systems due to  
stringent regulatory  
requirements.

**GxP Compliance &  
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Arbour Group also offers separate SAP validation and compliance solutions for SAP Business ByDesign and SAP Business One. SAP S/4HANA Business Suite Compliance. SAP

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Business Suite 4 SAP HANA is an ERP solution that has been developed to take advantage of SAP's in-memory computing platform, SAP HANA.

## **SAP Validation & Compliance | SAP S/4 HANA Validation**

...

The GMP categorisation is decided on the basis of the pertinent GMP guideline. The SAP ECC 6.0 ERP application

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software falls under the category 4 & 5-Configurable software packages as well as customised software as defined in GAMP 5 guidelines. The GAMP 5 categorisation and SAP ECC 6.0 system detail categorisations is summarised in Table 1.

**SAP ERP  
Implementation  
Strategy Validation  
Activity Before ...**

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understood, finishing  
does not suggest that  
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