

DATA PRIVACY

Key Facts and Solutions



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Healthcare Industry Partners

EU GDPR

5 signs
that your organisation
is all set on GDPR:

1 Expanded scope

Does your organisation process data or is it responsible for the processing of personal data in the EU or personal data belonging to EU citizens?

2 Accountability

Do you have a data protection programme in place (e.g. data protection officer) and are you able to demonstrate compliance with the requirements of the GDPR?

3 Duty of disclosure

Would you be able to notify the authorities of a data breach within 72 hours?

4 Built-in data protection

Are you integrating data protection and data protection requirements in the development of your business processes and new systems?

5 Additional rights

Can you ensure the “right to be forgotten”, the rights of data portability and the right to object to profiling?



Much stricter EU data protection regulation as of May 2018

This date marks the end of the implementation period for the EU directive on data protection (General Data Protection Regulation = GDPR). Thereafter, Europe and all the countries doing business with the EU will be subject to a new regulatory framework on data protection and privacy in the processing of personal data of EU citizens.

The directive applies to all organisations active in Europe, even if they have no branches in the EU.

What is GDPR, and who does it apply to?

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The following changes will be particularly challenging:

- The expanded definition of “personal data” IP addresses, user IDs, GPS data, mobile device identifiers (UDID = unique mobile device identifiers) and many other types of information will now be included under the definition of “personal data”.
- The detailed documentation of data protection measures such as the anonymization and encryption of personal data, the ability to ensure ongoing confidentiality, integrity and availability of processing systems and services, and much more.
- Complexity of implementing the “data subject request” and “data breach” processes required as per the GDPR, especially in the organisation’s IT management.

If your company holds data belonging to EU citizens and has not yet prepared for GDPR, the time to act is now!

Drastic consequences of non-compliance

- X Legal sanctions, fines, penalties, class action lawsuits
- X Potential loss of business relationships and risk of being completely blocked from entering the market (customers contractually shift responsibility for GDPR compliance)
- X Prolonged investigation or cessation of international data transfer

HGP as a competent partner in the life sciences sector

HGP Pharma Compliance offers you a structured GDPR preparation plan that is efficient and quick to implement. We utilise the fact that many requirements are already satisfied through the active management operations performed in your computer system validation process:

70% of compliance requirements are the same for pharma IT and GDPR!

As compliance experts in the pharmaceutical industry, we examine what is already in place and embed the GDPR requirements into your existing CSV compliance framework. We simply create a second framework to add to the existing one. This way, we achieve the desired compliance status while saving you time and money.



What HGP can do for you

GDPR 1-Day-Assessment

Our services:

High-level assessment in conjunction with a management workshop to determine your current compliance status with regard to the new GDPR requirements. Identification of the biggest risks and recommendations.

What you get:

An overview of your GDPR status in the form of a management report with the main findings of the assessment.

GDPR in-depth assessment

Our services:

Intensive audit in 1-1 workshops, surveys and interviews. Ascertainment of the GDPR compliance status of selected assets of your organisation.

What you get:

A detailed summary of the risks identified and an action plan.

Privacy impact assessment & data protection through design

Our services:

A PIA template individually tailored to your company. Interviews with the system/project managers, review of plans and documentation to assess the risk to the individual in case personal data are misused.

What you get:

A detailed assessment of your systems / projects in order to identify the main data protection risks and the steps necessary to manage personal information in compliance with GDPR.

Data Protection Officer (DPO) Service

Our services:

We provide the legally required data protection officer for an interim phase. This DPO represents you company before internal and external stakeholders and starts the implementation of your GDPR processes.

What you get:

A DPO with pharma compliance experience for the time period that is convenient to you.



Halfmann Goetsch Partner AG

St. Alban-Vorstadt 94
4052 Basel | Schweiz

Phone +41 61 544 00 00
info@hgp.ag | www.hgp.ag