

# Joint **A**udit **V**erfahren **f**ür *Joint **A**udit **V**enture for*

- 1) Manufacturers of excipients and process aids (JAVf**H**)
- 2) Manufacturers of packaging materials (JAVf**P**)
- 3) Logistic service providers (JAVf**L**)



# Who are we?

We are a non-trading partnership under the German Civil Code (German: *Gesellschaft bürgerlichen Rechts (GbR)*), constituted by currently 27 pharmaceutical companies of German speaking countries.

# Our Partners



- Abbott Laboratories GmbH
- Acino Pharma AG
- Aenova Holding GmbH
- Aesica Pharmaceuticals GmbH  
(Member of the Recipharm Group)
- Bayer AG
- Berlin-Chemie AG
- betapharm Arzneimittel GmbH  
(Member of the Dr. Reddy's Group)
- BIPSO GmbH
- Boehringer Ingelheim GmbH
- Corden Pharma GmbH
- Daiichi Sankyo Europe GmbH
- Desitin Arzneimittel GmbH
- Fidelio Healthcare Limburg GmbH
- Fresenius Kabi Deutschland GmbH
- Grünenthal GmbH
- Luye Pharma AG
- MCM Klosterfrau Vertriebs GmbH
- Medice Arzneimittel Pütter GmbH&Co KG
- Merck Healthcare KGaA
- Merckle GmbH  
(Member of the TEVA Group)
- Merz Pharma GmbH & Co KGaA
- Panpharma GmbH
- Rentschler Biopharma SE
- Rottendorf Pharma GmbH
- R-Pharm Germany GmbH
- Sanofi-Aventis Deutschland GmbH
- Vifor (International) Ltd.

# The purpose of our partnership



..... is conjoining resources and expertise for supplier audits and audits of distribution partners:

- to increase the willingness of our suppliers to accept audits by approaching them jointly
- to perform audits jointly and thus reduce the number of audits, in order to save our resources as well as those of our suppliers
- to make audit reports available to our partners and their affiliated companies without additional cost – with the consent of the audited companies

# The purpose of our partnership



We do not have any commercial interest  
but act with the exclusive aim to jointly fulfill  
GMP/GDP requirements.

# The partnership contract

Determines .....

- the aim of the partnership,
- JAV partnership conditions,
- management and administration,

and

- **obliges all partners to treat audit results confidentially.**

# The Annual Partners' Meeting

- defines the procedures for performing the audits
- if needed, adapts aims of the organization to altered conditions
- deals with events/issues which occurred during the preceding audit period
- lays down organizational details for the execution of the audits
- develops common GMP/GDP approaches to relevant issues
- is usually complemented by an advanced training session for auditors

# The Yearly Audit Plan

- Is elaborated in quarter 4 of every year
- Is based on pre-established audit frequencies by the JAV partners
- Strives for balanced participation of JAV partners in relation to downloaded audit reports



- Are typically performed by experienced auditors of two partner companies.
- Specifically focus on the requirements of our partners.
- Are performed according to a standard procedure using standard formats which have been developed by our partners.

Since the foundation of our initiative in the year 2001 we have performed about 950 audits and re-audits.

These cover:

- >200 manufacturers / traders / service providers
- >300 sites

(State end of 2020)

The audit documentation is filed in our data base.

Access to audit documents is exclusive to our partners and their related companies, starting from the date of their membership.

We strive for an average ratio between participation in an audit and access to audit reports of 1:3 to 1:4.

- Two-thirds majority of our partners agrees with your application
- Annual fee is currently 2.600 € per year

(year 2023)

# Interested in a membership?



You are welcome to join us if:

- ✓ You have a relatively broad congruence of common suppliers
- ✓ You are willing to perform joint audits with other JAV partners
- ✓ You are willing to actively participate in the further development of our initiative

**→ Please contact us!**

Please visit our website:

**[www.javfx.de](http://www.javfx.de)**

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