

Joint **A**udit **V**erfahren für *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 leading pharmaceutical companies of German speaking countries. The purpose of our partnership is to perform joint supplier audits.

- Abbott Laboratories GmbH
- Acino Pharma AG
- Aenova Holding GmbH
- Aesica Pharmaceuticals GmbH
- Bayer AG
- Berlin-Chemie AG
- betapharm Arzneimittel GmbH
- 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
- Merz Pharma GmbH & Co KGaA
- Nordmark Pharma GmbH
- Panpharma GmbH
- Rentschler Biopharma SE
- Rottendorf Pharma GmbH
- R-Pharm Germany GmbH
- Sanofi-Aventis Deutschland GmbH
- Siegfried AG
- Vifor (International) Ltd.

The purpose of our partnership

..... is conjoining resources – on our suppliers' part as well as on our part

- to make audit reports available to our partners and their affiliated companies without additional cost – with the consent of the audited companies
- to save time and costs
- to facilitate audits for those partners who only purchase small volumes

The purpose of our partnership

We are a **Non-Profit** partnership without any commercial interest

acting together with the exclusive aim to **jointly** comply with

GMP/GDP requirements.

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
- offers regular advanced training sessions for auditors

- 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 Operation Procedure.
- Audit reports are issued on standard formats in English language.

Since the foundation of our initiative in the year 2001 we have performed more than 1.000 audits and re-audits.

These cover:

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

(State end of 2023)

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.

- Generally high level of acceptance by the auditees.

Auditees get access to our website enabling them to verify which one of our partners has downloaded audit reports.

- Authorities

Authorities regularly check JAV audit reports. National as well as international authorities have checked and accepted our procedures.

- Your application for admission will be checked by all JAV partners
- Two-thirds majority of our partners has to agree with your application
- Annual fee is currently 2.600 € per year

(year 2024)

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 will in future forego individual audits of suppliers in our JAV portfolio
- ✓ You are willing to actively participate in the further development of our initiative

→ Please contact us!

Please visit our website:

www.javfx.de

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