

Special Terms and Conditions “Zero to Hero On-Demand”

Johner Institut GmbH · Reichenaustraße 39a · 78467 Konstanz, Germany

Version: October 2026

One important thing first: your satisfaction matters a great deal to us. If, for whatever reason, you have cause to complain about our services, please let us know. We will find a solution together!

Preamble

These Special Terms and Conditions govern participation in the “Zero to Hero On-Demand” professional training programme of Johner Institut GmbH (hereinafter: the “Programme”). They supplement the General Terms and Conditions of Johner Institut GmbH (Part I), which are available at www.johner-institut.de/agb and remain part of the contract. The programme-specific services, activation dates, packages and prices are set out in the programme description on the programme page valid at the time of the order and in the order confirmation.

In the event of conflicts between the General Terms and Conditions (Part I) and these Special Terms and Conditions, the provisions of these Special Terms and Conditions shall prevail. In relation to the General Terms and Conditions (Part I), the programme description shall be deemed part of these Special Terms and Conditions.

§ 1 Scope

1.1 These Special Terms and Conditions apply to participation in the “Zero to Hero On-Demand” programme of Johner Institut GmbH, Reichenaustraße 39a, 78467 Konstanz, Germany (hereinafter: “Johner Institut”). By placing an order, the contracting party (hereinafter: “Participant”) agrees to the application of these Special Terms and Conditions and of the General Terms and Conditions (Part I). Where a natural person designated by the Participant uses the access, that person is referred to as the “participating person”. Obligations which by their nature can only be fulfilled by a natural person are incumbent on the participating person. The Participant is responsible for their compliance pursuant to Section 278 of the German Civil Code (BGB). In certain provisions of these Special Terms and Conditions, the Participant is also referred to as the “Company” or the “Customer”. In each case, this means the same contracting party.

1.2 The Programme is aimed exclusively at entrepreneurs within the meaning of Section 14 BGB. Purchase by consumers within the meaning of Section 13 BGB is excluded. When placing the order, the

contracting party warrants that it is acting in the exercise of its commercial or independent professional activity. If this assurance proves to be incorrect, Johner Institut may terminate the contract for good cause.

1.3 Deviating terms and conditions of the Participant shall not apply. This shall also apply if Johner Institut does not expressly object to their inclusion.

1.4 The version of these Special Terms and Conditions valid at the time the contract is concluded shall be authoritative.

1.5 Ordering via the online shop is open exclusively to small and medium-sized enterprises within the meaning of Recommendation 2003/361/EC of the European Commission: fewer than 250 employees and an annual turnover not exceeding EUR 50 million or an annual balance sheet total not exceeding EUR 43 million. Linked and partner enterprises are to be included in accordance with this Recommendation. The Participant warrants this status when placing the order. Johner Institut checks the information before accepting the order.

1.6 If the Participant does not meet the requirements under paragraph 5, Johner Institut shall reject the order. If it only becomes apparent after conclusion of the contract that the assurance under paragraph 5 was incorrect, Johner Institut may terminate the contract for good cause. In both cases, it refunds any remuneration already paid and deactivates any accesses already set up. On request, it will make the Participant an offer for a company licence via its sales team.

§ 2 Description of Services

2.1 "Zero to Hero On-Demand" is a self-study professional training offering of Johner Institut GmbH on artificial intelligence in the regulatory environment of medical devices. It is offered in two packages: "Make" (Programme) and "Buy" (Programme plus further, fully worked-out review aspects pursuant to paragraph 8). The format, activation dates, packages and specific components are set out in the programme description on the programme page valid at the time of the order.

2.2 The Programme contains the following components:

- (a) Video modules with assignments, model solutions and self-tests, provided via a learning platform.
- (b) Lessons-learned videos: short videos on common problems in the programme work.
- (c) Accompanying materials and base IP (review criteria, data structures and scripts for the review aspects covered in the Programme) and a fictitious sample product pursuant to paragraph 7.
- (d) Support by e-mail pursuant to paragraph 9.
- (e) In the "Buy" package: further review aspects pursuant to paragraph 8.
- (f) A certificate of attendance pursuant to § 7.

2.3 Which of the above components form part of the specific Programme, and to what extent, is determined by the programme description on the programme page valid at the time of the order and by the order confirmation. In the event of conflicts between the programme description and these Special Terms and Conditions, these Special Terms and Conditions shall prevail.

2.4 Johner Institut reserves the right to change individual content or formats (in particular video modules and lessons-learned videos), provided that this does not materially change the overall character of the Programme. It may postpone individual activation dates for good cause and will give timely notice of this.

2.5 Participation in the Programme and the certificate of attendance do not constitute a state-recognised qualification. They do not replace any official qualification, academic degree or IHK (Chamber of Industry and Commerce) certification. A certificate is not part of the Programme. Johner Institut gives no guarantee that participation in the Programme will bring any particular professional advantages.

2.6 The Programme teaches how to build an AI-supported tool to assist in the review of technical documentation. The tool created in the process is a learning and practice result. No particular result of work is owed.

2.7 The programme work, including building the tool pursuant to paragraph 6, is carried out on a fictitious sample product provided by Johner Institut together with the associated sample documentation. The Programme can be completed in full using this sample product alone. The Company's own documents are not included. Details are governed by § 15 paragraph 1.

2.8 In the "Buy" package, the Participant additionally receives eleven (11) further, fully worked-out review aspects (in particular review criteria, JSON schemas and review prompts) for use in the tool built in the Programme. Johner Institut will inform the Participant of the time and form of provision. § 9 applies to the rights of use.

2.9 Johner Institut answers questions from the participating person about the organisation and technology of the Programme by e-mail within two (2) working days. Personal support, live sessions and individual expert advice are not part of the Programme.

§ 3 Conclusion of Contract

3.1 By submitting the order via the online order form, the Participant makes a binding offer to conclude a contract. In doing so, the Participant confirms that it has taken note of and accepts these Special Terms and Conditions and the General Terms and Conditions (Part I).

3.2 The contract is concluded when Johner Institut, after checking the requirements under § 1 paragraph 5, accepts the order by sending an order confirmation by e-mail.

3.3 The language of the contract is German. Johner Institut confirms the order by e-mail. The confirmation reflects the essential content of the contract.

§ 4 Access and Obligations of the Participant

4.1 Access to the learning platform with the video modules is provided by creating a participant account. The access credentials are sent by e-mail at the programme start.

4.2 The access credentials are personal and non-transferable. They are valid exclusively for the registered participant.

4.3 The Participant is obliged to keep the access credentials and passwords secret and to prevent unauthorised use by third parties. In the event of misuse, Johner Institut is entitled to block access. The Participant is liable for any misuse for which it is responsible.

4.4 The Participant is responsible for meeting the technical requirements for participation, in particular a stable internet connection, up-to-date browser software and a computer on which the applications required for the AI work environment may be installed.

4.5 The Participant itself is at all times responsible for ensuring the regulatory compliance of products developed or adapted with the help of the knowledge acquired in the Programme.

§ 5 Scope of Services and Availability

5.1 Johner Academy: Access to the Johner Academy is not included in the scope of services. It can be booked separately as an add-on. The General Terms and Conditions – Auditgarant, Johner Academy & Johner MDR Basics (Part III) apply to it.

5.2 Activation and availability: The video modules are activated step by step from the programme start stated in the programme description. They are available for twelve (12) months from activation. A community is not part of the Programme.

5.3 Johner Institut is entitled to further develop, update and reasonably modify the content of the Programme. If a change leads to a material restriction of the Programme, the Participant is entitled to terminate the contract without notice. The right of termination may be exercised within six (6) weeks of the material restriction taking effect.

5.4 Johner Institut gives no warranty regarding regulatory compliance or the passing of audits or inspections by notified bodies, authorities or other regulatory bodies.

5.5 The scope of services further includes personal access to the AI work environment pursuant to § 14.

§ 6 On-Site Day

6.1 The Programme does not include an on-site day.

§ 7 Certificate of Attendance

7.1 A certification examination is not part of the Programme.

7.2 After completing all self-tests of the video modules, the participating person receives a certificate of attendance.

7.3 The certificate of attendance is Johner Institut GmbH's own document. It does not constitute a state-recognised qualification, an academic degree or an IHK (Chamber of Industry and Commerce) certification.

§ 8 Video Modules

8.1 The video modules are based on the content of the live programme "Zero to Hero – the Fast Track". Johner Institut may revise them and, where needed, re-record and edit them. They do not contain contributions or images of participants of the live programme.

8.2 There is no entitlement to particular content, lengths or formats of the videos. The programme description is authoritative.

8.3 The videos may only be accessed by the participating person for their own use. Downloading, recording and passing on are not permitted.

8.4 Data protection information on the use of the learning platform can be found in the data protection information for participating persons.

§ 9 Intellectual Property and Rights of Use

9.1 All content provided within the Programme (video modules, lessons-learned videos, materials, templates, base IP and, in the "Buy" package, the further review aspects) is protected by copyright. All rights established thereby, in particular the exploitation rights under Sections 15 to 23 of the German Copyright Act (UrhG), are reserved to Johner Institut or to the authors and licence holders.

9.2 The Participant receives a simple (non-exclusive), unlimited, non-transferable right to use the content provided for its own use.

9.3 The following in particular are not permitted:

- a) passing on, selling, renting or lending content,
- b) reproducing, publishing or distributing content (videos, downloads, materials) in any form,
- c) using content to create one's own commercial training offerings, and
- d) using content, including the review aspects, for services to third parties, in particular in consulting or customer projects.

9.4 Johner Institut assigns to the Company any rights to outputs generated by the participating person that Johner Institut acquires under the Provider's terms (§ 14 paragraph 1). Johner Institut acquires no rights to the content entered by the participating person or to the checklists, schemas, scripts and reports generated from it. Paragraphs 1 to 3 remain unaffected for Johner Institut's programme material. The rights to the programme material do not extend to the results that the participating person creates using this material.

§ 10 Remuneration and Payment

10.1 The remuneration for participation in the Programme is the price shown on the programme page at the time of the order. All prices are exclusive of statutory VAT.

10.2 Unless otherwise agreed in the offer, the remuneration is due in full as a one-off payment upon conclusion of the contract.

10.3 Payment is made by bank transfer or via the payment methods offered in the ordering process. Unless otherwise agreed, invoices are payable within fourteen (14) days without deduction.

10.4 In the event of default in payment, Johner Institut is entitled to block access to the content and to charge default interest in accordance with Section 288 (2) BGB.

§ 11 Contract Term and Termination

11.1 Programme: The contract for participation in the Programme has a fixed term of twelve (12) months from the programme start. It ends automatically without notice of termination. Ordinary termination is excluded. The term of access to the AI work environment is governed by § 14 paragraph 9.

11.2 Johner Academy: Access to the Johner Academy booked separately is governed by the terms applicable to it (§ 5 paragraph 1).

11.3 The right to extraordinary termination for good cause remains unaffected. The requirements of Section 314 (2) BGB (period for remedy or warning, unless dispensable) apply unchanged. Good cause for Johner Institut exists in particular if:

(a) the Participant is more than 30 days in arrears with payment despite a reminder,

(b) the Participant violates § 9 (Intellectual Property),

(c) the Participant uses the learning platform or the AI work environment for unlawful, offensive or discriminatory purposes, or

(d) the assurance under § 1 paragraph 5 proves to be incorrect (§ 1 paragraph 6).

11.4 Cancellation after conclusion of the contract is excluded. There is no statutory right of withdrawal, as the Programme is aimed exclusively at entrepreneurs (§ 1 paragraph 2). The right to extraordinary termination under paragraph 3 and the right of termination under § 5 paragraph 3 remain unaffected.

§ 12 Liability

12.1 In all cases of contractual and non-contractual liability, Johner Institut is liable to the Participant for intent and gross negligence in accordance with the statutory provisions for damages or reimbursement of futile expenses.

12.2 In other cases, Johner Institut is only liable for breach of a material contractual obligation (cardinal obligation), and only for compensation of foreseeable and typical damage. In all other cases, the liability of Johner Institut is excluded, subject to the provision in para. 3.

12.3 Liability for damage resulting from injury to life, body or health and under the German Product Liability Act remains unaffected by the above limitations and exclusions of liability.

12.4 Liability cap: The total liability of Johner Institut arising from and in connection with the contract is limited to the amount of the remuneration paid by the Participant. By way of derogation, for damage resulting from breach of the obligations under § 14 paragraph 6, a cap of three times the remuneration paid applies. This corresponds to the cap that applies under § 15 paragraph 5 to Johner Institut's claims against the Company. This does not apply in the cases of paras. 1 and 3.

12.5 Participation in the Programme does not replace individual legal, regulatory or technical advice. Johner Institut accepts no liability for decisions made by the Participant on the basis of the content taught in the Programme.

§ 13 Artificial Intelligence (AI)

13.1 AI-supported tools and demonstrations are used within the Programme.

13.2 The Programme is conducted in an AI work environment provided by Johner Institut. §§ 14 and 15 apply to it. They conclusively govern which settings Johner Institut makes, which obligations the Company and the participating persons have when entering content, and which assurances Johner Institut does not give.

13.3 Despite careful development, AI models may deliver incorrect results. Johner Institut accepts no liability for decisions made by the Participant on the basis of AI-generated information.

§ 14 AI Work Environment Provided by Johner Institut

14.1 Johner Institut provides an AI work environment for the Programme. It is based on a commercial service of Anthropic Ireland, Limited, Dublin, Ireland (hereinafter the “Provider”). This section and § 15 apply to it.

14.2 The AI work environment consists of personal access to an organisation at the Provider managed by Johner Institut and the Provider’s applications to be run on the participating person’s computer. The access included in the Programme is a non-independent component of the programme service. It is priced neither as a separate service nor according to the extent of use. There is no independent entitlement to the access. Paragraph 9 applies to a paid extension.

14.3 The access serves the purpose of working on the programme content, exercises and project work during its term pursuant to paragraph 9. The scope of use is limited. Use for other business purposes or for third parties is therefore at the expense of the Programme and is not permitted.

14.4 The access is tied to the person designated by the Company and is non-transferable. The Company shall inform Johner Institut without undue delay if a designated person leaves the Company or no longer participates. In this case, Johner Institut is entitled to deactivate the access. The designation of a replacement is governed by § 16 paragraph 3.

14.5 The Provider’s applications run on the participating person’s computer. Data traffic takes place directly between these applications and the Provider. Johner Institut does not operate any infrastructure of its own in the data path and does not take note of the content processed. As owner of the organisation, it would technically be able to access entered content. It does not do so. It manages the organisation at the Provider and makes the settings pursuant to paragraph 6.

14.6 Johner Institut configures the organisation, based on the Provider functions available at the start of the Programme, such that

- a) login is tied to the organisation managed by Johner Institut,
- b) functions for transmitting feedback, bug reports and session content to the Provider are deactivated, to the extent they can be controlled centrally,
- c) connectors to external systems and web search are deactivated, and
- d) under the Provider’s commercial terms, no training of models with the entered content takes place, and Johner Institut does not consent to such use.

Johner Institut makes these settings in performance of the agreement with the Company. Johner Institut shall provide evidence of the settings made in a suitable form at the Company’s request. This does not constitute any assurance regarding the Provider’s conduct. § 15 paragraph 7 applies accordingly.

14.7 The scope of services is designed for the usual work on the programme content. Johner Institut is entitled to set, for each participating person, a usage cap equal to three times the average usage of all participating persons of the same programme run in the respective calendar month, but at least the usage provided by the Provider for the selected access type. The applicable usage is visible to the participating person in the work environment. A limitation does not have retroactive effect. The rest of the programme operation, in particular video modules, materials and model solutions, remains unaffected. On request, Johner Institut may provide an extended scope in return for a reasonable contribution to costs. There is no entitlement to this.

14.8 Instead of the access provided, the participating person may use their employer's own access to a suitable service. In this case, Johner Institut is neither in the data path nor does it process usage data of this person. Only the terms between the Company and its provider apply. The obligations under § 15 and the liability provisions remain unaffected.

14.9 The access exists for the term stated in the programme description; for the programme run starting on 1 Dec 2026, until 31 Mar 2027. The Participant may extend it for a fee by four (4) months at a time. The price is shown in the online shop at the time of the order. There is no automatic extension. Without an extension, the access ends when the respective term expires. The participating person shall back up their work results independently by then. These are stored on their computer; however, access to history data stored at the Provider ends. There is no entitlement to continued access.

14.10 Johner Institut does not guarantee any particular availability of the service, any particular models or any particular quality of responses. Outages and changes at the Provider, in particular to models, usage limits and prices, are beyond its control.

§ 15 Work on the Sample Product, Obligations and Indemnification

15.1 The programme work is carried out exclusively on the sample product pursuant to § 2 paragraph 7. The inclusion of the Company's own documents in the AI work environment is excluded. Johner Institut provides the sample product together with the associated sample documentation to an extent that enables the Programme to be carried out without the Company's own documents.

15.2 The Company shall ensure that no personal data and no documents subject to a confidentiality obligation towards a third party are entered into the AI work environment. Each designated participating person works exclusively in the access provided and in compliance with the Provider's usage policies. The use of private accounts with the Provider is prohibited, as different terms with a different training regime apply to them. If, contrary to paragraph 1 or sentence 1, documents or personal data are nevertheless entered, the Company shall notify Johner Institut without undue delay. Upon becoming aware of this, Johner Institut shall work towards deletion without undue delay, insofar as the Provider's functions permit.

15.3 The Company undertakes to ensure that each participating person designated by it complies with the obligations under paragraphs 1 and 2 and under § 14 paragraph 3 and paragraph 4. It is responsible for any fault of these persons pursuant to Section 278 BGB to the same extent as for its own fault. Before the first use of the AI work environment, the Company shall provide each designated participating person with the data protection information for participating persons provided by Johner Institut.

15.4 If the Company or a participating person designated by it breaches the obligations under paragraph 1 or paragraph 2, the Company shall indemnify Johner Institut against claims asserted by third parties against Johner Institut arising from or in connection with this breach, including the reasonable costs of legal defence. This covers in particular amounts that Johner Institut has to pay on the basis of its own indemnification obligation towards the Provider. This indemnification does not apply

a) to the extent that the claim is based on a breach of duty by Johner Institut, on intent or gross negligence on the part of Johner Institut, or on a breach of § 14 paragraph 6,

b) to the extent that the claim is based on content provided by Johner Institut itself, in particular on the sample product and the programme material, or on the service and its outputs, and

c) to the extent that Johner Institut has violated the Company's rights of participation under paragraph 6, although exercising them was possible.

15.5 Johner Institut's claims under paragraph 4 are limited per contract to a total of three times the remuneration paid for the contract concerned. The limitation does not apply if the Company or a participating person designated by it acted intentionally. Johner Institut's own indemnification obligation towards the Provider is not limited in amount. Johner Institut itself bears the portion exceeding the above maximum amount.

15.6 The Company shall notify Johner Institut without undue delay as soon as it becomes aware of circumstances that may give rise to a claim under paragraph 4. Johner Institut shall notify the Company of such a claim without undue delay and give it the opportunity to participate in the legal defence at its own expense. The conduct of the legal defence, including the choice of legal representation and the decision on a settlement, remains with Johner Institut, insofar as this corresponds to its obligations towards the Provider. Johner Institut shall take the Company's interests into appropriate account. If a party breaches its duty to notify or cooperate and the legal defence is thereby materially impaired, the obligations of the other party lapse to the extent caused thereby.

15.7 Johner Institut makes the settings pursuant to § 14 paragraph 6 and does not consent to the use of the entered content for training purposes. There is no assurance regarding the Provider's actual conduct, regarding processing exclusively within the European Union, or that no data whatsoever is stored. There is no EU data residency for the service used. Johner Institut does not take note of the entered content and therefore cannot guarantee that no personal data is entered. The participating person is obliged to

ensure this pursuant to paragraph 2. Details on data processing can be found in the data protection information for participating persons.

15.8 The liability cap pursuant to § 12 paragraph 4 applies exclusively to claims of the Company against Johner Institut. It does not limit Johner Institut's claims under paragraph 4. Paragraph 5 applies to those. These paragraphs establish compensation exclusively in the internal relationship. Claims of third parties and measures by supervisory authorities against Johner Institut, the Company or the participating person remain unaffected, and Johner Institut cannot invoke this internal compensation towards third parties.

§ 16 Designated Persons and Several Places

16.1 Johner Institut's contracting party is the booking Customer. Each place is for one natural person. When ordering, the Customer shall provide Johner Institut with the name and business e-mail address of the participating person. If it books several places, this applies to each person.

16.2 The access credentials of the individual participants are personal and non-transferable. § 4 paragraph 2 and paragraph 3 and § 14 paragraph 4 apply accordingly to each designated person.

16.3 If a designated person leaves the Customer during the term, the Customer is entitled to designate a replacement person once per person. It shall ensure that the departing person has no further access to programme content and access credentials, and shall notify Johner Institut of the departure without undue delay.

16.4 Splitting the places between different companies or third parties outside the group is excluded. The same applies to access to the AI work environment.

§ 17 Data Protection

17.1 Johner Institut processes the Participant's personal data for the performance of the contract pursuant to Art. 6(1)(b) GDPR. Details can be found in the privacy policy at www.johner-institut.de/datenschutz. For personal data of participating persons, the data protection information for participating persons pursuant to § 15 paragraph 3 takes precedence.

17.2 Art. 6(1)(b) GDPR (performance of contract) applies to the provision of the video modules via the learning platform. Details can be found in the data protection information for participating persons.

§ 18 Final Provisions

18.1 Unless these Special Terms and Conditions contain deviating provisions, the General Terms and Conditions (Part I) of Johner Institut GmbH apply additionally.

18.2 Legal disputes arising from or in connection with this contract are governed exclusively by German law, excluding the provisions of private international law and excluding the UN Convention on Contracts for the International Sale of Goods.

18.3 For entrepreneurs or persons without a permanent residence in Germany, the exclusive place of jurisdiction for legal disputes arising from or in connection with this contract is Konstanz.

18.4 Supplementary or deviating agreements require text form to be effective.

18.5 Should any provision of this contract be or become invalid, the validity of the remaining provisions shall remain unaffected.