

Special Terms and Conditions “Zero to Hero – the Fast Track”

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

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Non-binding English translation. The German version of these Special Terms and Conditions is the sole authoritative and legally binding text (§ 3.3). In the event of any discrepancy, the German version prevails.

One important note first: Your satisfaction matters greatly to us. Should you have any reason to complain about our services, for whatever reason, please talk to us. We will find a solution together!

Preamble

These Special Terms and Conditions govern participation in the continuing education program “Zero to Hero – the Fast Track” of Johner Institut GmbH (hereinafter: the “Program”). They supplement the General Terms and Conditions of Johner Institut GmbH, which are available at www.johner-institut.de/agb and remain part of the contract. The program-specific services, dates, packages and prices follow from the program description on the program page valid at the time of the order and from the order confirmation.

In the event of contradictions between the General Terms and Conditions and these Special Terms and Conditions, the provisions of these Special Terms and Conditions prevail. In relation to the General Terms and Conditions, the program description is deemed part of these Special Terms and Conditions.

§ 1 Scope of application

1.1 These Special Terms and Conditions apply to participation in the program “Zero to Hero – the Fast Track” of Johner Institut GmbH, Reichenaustraße 39a, 78467 Konstanz, Germany (hereinafter: the “Johner Institute”). By placing the order, the contracting party (hereinafter: the “Participant”) agrees to the application of these Special Terms and Conditions and of the General Terms and Conditions. Where a natural person named by the Participant uses the access, that person is referred to as the “Participating Individual”. Obligations which by their nature can only be fulfilled by a natural person are incumbent on the Participating Individual. The Participant is responsible for compliance with these obligations pursuant to § 278 BGB (German Civil Code). In individual provisions of these Special Terms and Conditions, the Participant is also referred to as the “Company” or as the “Customer”. The same contracting party is meant throughout.

1.2 The program is directed exclusively at entrepreneurs within the meaning of § 14 BGB. Purchase by consumers within the meaning of § 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 warranty proves to be incorrect, the Johner Institute may terminate the contract for good cause.

1.3 Deviating terms of the Participant do not apply. This also applies if the Johner Institute 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 is authoritative.

§ 2 Description of services

2.1 “Zero to Hero – the Fast Track” is a continuing education offering of Johner Institut GmbH on artificial intelligence in the regulatory environment of medical devices. Format, dates, packages and specific components follow from the program description on the program page valid at the time of the order.

2.2 All programs have in common that they may contain the following components in whole or in part, whereby lit. (a) may, by way of derogation, only ever be booked as a separate additional service pursuant to § 5 (1) and is not part of a package:

(a) Online courses / video lessons of the Johner Academy on AI and MedTech regulatory topics, bookable optionally as an additional service (§ 5 (1)).

(b) Live online sessions, workshops or expert sessions, conducted via Microsoft Teams or a comparable video conferencing platform. Live sessions may be recorded and made available to participants afterwards.

(c) Access to a closed online community for exchange with other participants and instructors during the program term.

(d) Accompanying materials (e.g. prompt library, curated reading lists, templates).

(e) Optional: One on-site day in Konstanz (only where expressly stated in the program description).

(f) Optional: A certification examination in accordance with the program description. The examination regularly consists of multiple-choice questions and a practical submission.

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

2.4 The Johner Institute reserves the right to adjust individual instructors, content or formats (in particular of live sessions and, where applicable, on-site days), provided this does not substantially

change the overall character of the program. It may reschedule individual dates for good cause and will give timely notice thereof. This applies accordingly to the start of the program.

2.5 Participation in the program and obtaining a certificate issued within the program do not constitute a state-recognized qualification. These are the Johner Institute's own certificates. They confirm competences within the meaning of the requirements of ISO 13485 and the AI Act, but do not replace any official qualification, any academic degree or any certification by a German Chamber of Industry and Commerce (IHK). The Johner Institute gives no warranty that participation in the program or obtaining the certificate will bring about any particular professional advantages.

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

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

§ 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.

3.2 The contract comes into effect when the Johner Institute accepts the order by sending an order confirmation by email.

3.3 The language of the contract is German. The Johner Institute confirms the order by email. The confirmation reflects the essential content of the contract.

§ 4 Access and obligations of the Participant

4.1 Access to the online courses and the community is enabled by creating a participant account. The access credentials are transmitted by email after the contract is concluded.

4.2 The access credentials are personal and non-transferable. They apply exclusively to the registered Participant.

4.3 The Participant is obliged to keep the access credentials and passwords confidential and to prevent unauthorized use by third parties. In the event of misuse, the Johner Institute is entitled to block the 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 microphone and camera for live sessions.

4.5 The Participant itself is responsible at all times for ensuring the regulatory conformity of products that are developed or adapted using the knowledge acquired in the program.

§ 5 Scope of services and availability

5.1 Johner Academy: Access to the Johner Academy (e-learning platform) is not part of the scope of services of the program. It may be booked as a separate additional service in accordance with the program description valid at the time of the order. If it is booked, the terms for Auditgarant, Johner Academy and Johner MDR Basics published at www.johner-institut.de/agb apply to it, including the provisions on term and termination set out therein. Details are governed by § 11 (2).

5.2 Access to the community pursuant to § 2 (2) lit. (c) exists for the duration of the program term.

5.3 The Johner Institute is entitled to further develop, update and reasonably modify the content of the program. If a change leads to a substantial restriction of the program, the Participant is entitled to terminate the contract without notice. This right of termination may be exercised within six (6) weeks from the occurrence of the substantial restriction.

5.4 The Johner Institute gives no warranty as to regulatory conformity or as to passing audits or examinations by notified bodies, authorities or other regulatory instances.

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

§ 6 On-site day (where stated in the program description)

6.1 If the program description provides for an on-site day, it takes place in Konstanz on a date determined by the Johner Institute. If it does not provide for an on-site day, § 6 does not apply.

6.2 Travel and accommodation costs for the on-site day are borne by the Participant. Included in the scope of services are: participation in the day's program (intensive session, strategy workshop, networking), conference beverages, lunch and a joint dinner.

6.3 If the Participant is unable to attend the on-site day, there is no claim to reimbursement of a pro rata fee or of the price difference to the basic package. The Johner Institute will endeavour to offer the Participant a digital participation option as an alternative, but is not obliged to do so.

6.4 The Johner Institute reserves the right to convert the on-site day into a digital format or to postpone it for good cause (e.g. force majeure, official orders, insufficient number of participants). In the event of

a postponement, the Johner Institute will communicate a new date for the on-site day. In the event of conversion into a digital format, the Participant will additionally be offered a replacement date for an on-site delivery upon request.

§ 7 Certification

7.1 If the program description provides for a certification examination, participants have the opportunity to sit it. The examination comprises multiple-choice questions and a practical submission. The type, scope and assessment criteria of the examination are communicated at least four (4) weeks before the examination date. If the program description does not provide for a certification examination, § 7 does not apply.

7.2 If the examination is not passed, the Participant receives one (1) free retake opportunity within three (3) months of the first examination date. Further retakes are subject to a charge.

7.3 The certificate is the Johner Institute's own certificate. It confirms competences within the meaning of ISO 13485 and the AI Act, but does not constitute a state-recognized qualification, an academic degree or a certification by a German Chamber of Industry and Commerce (IHK).

7.4 Participants who do not sit an examination or who do not pass it receive a certificate of attendance after completing the program.

§ 8 Recording of live sessions

8.1 Live sessions pursuant to § 2 (2) lit. (b) may be recorded by the Johner Institute and made available to participants via the platform. There is no claim to recording or to provision.

8.2 If a live session is recorded, the Johner Institute gives notice of this before it begins. Participants who do not wish to appear in the recording may deactivate their camera and take part under a pseudonym.

8.3 The recordings serve exclusively to be made available to other program participants. Any use beyond this (e.g. for marketing purposes) takes place only with the separate consent of the participants who are visible.

8.4 Information on the processing of personal data in connection with the live sessions under data protection law follows from the Johner Institute's privacy policy.

§ 9 Intellectual property and rights of use

9.1 All content provided within the program (online courses, live session recordings, materials, templates, community content of the Johner Institute) is protected by copyright. All rights arising therefrom, in particular the exploitation rights under §§ 15 to 23 UrhG (German Copyright Act), are reserved to the Johner Institute or to the authors and licence holders.

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

9.3 The following are in particular not permitted:

- a) passing on, selling, renting out or lending content,
- b) reproducing, publishing or distributing content (videos, downloads, materials) in any form, and
- c) using content to create one's own commercial training offerings.

9.4 The Johner Institute assigns to the Company the rights to the outputs generated by the Participating Individual which the Johner Institute acquires under the provider's terms (§ 14 (1)). The Johner Institute acquires no rights to the content entered by the Participating Individual or to the checklists, schemas, scripts and reports generated from it. Paragraphs 1 to 3 remain unaffected with regard to the Johner Institute's program material. The rights to the program material do not extend to the results which the Participating Individual creates using this material.

§ 10 Remuneration and payment

10.1 The remuneration for participation in the program follows from the price shown on the program page at the time of the order. All prices are exclusive of statutory value added tax.

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

10.3 Payment is made by bank transfer or via the payment methods offered in the ordering process. Invoices are to be settled within fourteen (14) days without deduction, unless a deviating agreement has been made.

10.4 In the event of default of payment, the Johner Institute is entitled to block access to the content and to charge default interest pursuant to § 288 (2) BGB.

§ 11 Contract term and termination

11.1 Program: The contract for participation in the program has the fixed term stated in the program description, beginning with the start of the program. It ends automatically without termination. Ordinary termination during the program term is excluded.

11.2 Johner Academy: If access to the Johner Academy is booked as an additional service pursuant to § 5 (1), the terms for Auditgarant, Johner Academy and Johner MDR Basics published at www.johner-institut.de/agb apply to its term and termination. Those terms currently provide for a minimum term of one (1) year from activation and a notice period of one (1) month to the end of the respective contract term. If no timely termination is given, the access is extended by one further year in each case.

Termination may be given in writing to the Institute's address, by email to elearning@johner-institut.de, or online in the Johner Academy customer account. The additionally booked Academy access continues irrespective of the end of the program term under paragraph 1. It does not end automatically with the program.

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

- (a) the Participant is more than 30 days in default of payment despite a reminder,
- (b) the Participant breaches § 9 (intellectual property),
- (c) the Participant uses the community or live sessions for unlawful, insulting or discriminatory purposes.

11.4 The Participant may terminate the contract in text form up to four (4) weeks before the start of the program. No fee is charged. Receipt of the declaration by the Johner Institute is decisive. If the start of the program is postponed, this period is postponed accordingly. Thereafter the contract continues. The right to extraordinary termination pursuant to paragraph 3 remains unaffected.

§ 12 Liability

12.1 The Johner Institute is liable to the Participant in all cases of contractual and non-contractual liability in the event of intent and gross negligence in accordance with the statutory provisions for damages or reimbursement of futile expenditure.

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

12.3 Liability for damage arising 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 the Johner Institute arising from and in connection with the contract is limited to the amount of the remuneration paid by the Participant. For damage arising from breach of the obligations under § 14 (6), a cap of three times the remuneration paid applies by way of derogation. It thereby corresponds to the cap that applies under § 15 (5) to the claims of the Johner Institute against the Company. This does not apply in the cases of paragraphs 1 and 3.

12.5 Participation in the program does not replace individual legal, regulatory or technical advice. The Johner Institute accepts no liability for decisions which the Participant takes on the basis of the content conveyed in the program.

§ 13 Artificial intelligence (AI)

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

13.2 The program is conducted in an AI working environment provided by the Johner Institute. §§ 14 and 15 apply to it. They govern conclusively which settings the Johner Institute makes, which obligations the Company and the Participating Individuals have when entering content, and which assurances the Johner Institute does not give.

13.3 Despite careful development, AI models may deliver erroneous results. The Johner Institute accepts no liability for decisions which the Participant takes on the basis of AI-generated information.

§ 14 AI working environment provided by the Johner Institute

14.1 The Johner Institute provides an AI working environment for the program. It builds on a commercial service of Anthropic Ireland, Limited, Dublin, Ireland (hereinafter the “provider”). This section and § 15 apply to it.

14.2 The AI working environment consists of personal access to an organization managed by the Johner Institute at the provider, together with the provider’s applications to be run on the Participating Individual’s computer. The access is a non-independent component of the program service. It is priced neither as a separate service nor according to the extent of use. There is no independent claim to the access.

14.3 The access serves to work on the program content, exercises and project work during the program term. The scope of use is limited. Use for other business purposes or for third parties is therefore at the expense of the program and is not permitted.

14.4 The access is tied to the person named by the Company and is non-transferable. The Company shall inform the Johner Institute without undue delay if a named person leaves the Company or ceases to participate. In this case the Johner Institute is entitled to deactivate the access. Naming a replacement is governed by § 16 (3).

14.5 The provider’s applications run on the Participating Individual’s computer. Data traffic takes place directly between these applications and the provider. The Johner Institute operates no infrastructure of its own in the data path and takes no knowledge of the content processed. As the owner of the organization, technical access to entered content would be possible for it. It does not exercise such access. It administers the organization at the provider and makes the settings pursuant to paragraph 6.

14.6 The Johner Institute configures the organization, according to the state of the provider’s functions available at the time the program begins, such that

a) sign-in is tied to the organization managed by the Johner Institute,

- b) functions for transmitting feedback, error 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 takes place using the entered content, and the Johner Institute does not consent to such use.

The Johner Institute makes these settings in performance of the agreement with the Company. Upon the Company's request, the Johner Institute will evidence the settings made in a suitable form. No assurance as to the provider's conduct is associated with this. § 15 (7) applies accordingly.

14.7 The scope of services is designed for the customary processing of the program content. The Johner Institute is entitled to set, for each Participating Individual, an upper limit of usage corresponding to three times the average usage of all Participating Individuals of the same program run in the respective calendar month, but at least the scope provided by the provider for the selected access type. The applicable scope is visible to the Participating Individual in the working environment. A limitation has no retroactive effect. The remainder of the program operation, live sessions, tutorials, materials and sample solutions, remains unaffected. Upon request, the Johner Institute may provide an extended scope against a reasonable contribution to costs. There is no claim to this.

14.8 Instead of the access provided, the Participating Individual may use their employer's own access to a suitable service. In this case the Johner Institute is neither in the data path nor does it process usage data of that 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 ends with the end of the program term. Until then, the Participating Individual secures their work results independently. These are located on their computer; access to history data stored at the provider ends, however. There are no claims to continuation of the access.

14.10 The Johner Institute gives no assurance as to any particular availability of the service, nor as to particular models or a particular quality of responses. Outages as well as changes at the provider, in particular to models, usage limits and prices, are outside its sphere of influence.

§ 15 Work on the sample product, obligations and indemnification

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

15.2 The Company ensures that no personal data and no documents subject to an obligation of confidentiality towards a third party are entered into the AI working environment. Each named

Participating Individual 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 to them, as deviating terms with a different training regime apply to these. If, contrary to paragraph 1 or sentence 1, documents or personal data are nevertheless entered, the Company shall notify the Johner Institute without undue delay. Once aware, the Johner Institute shall work towards deletion without undue delay, to the extent the provider's functions permit this.

15.3 The Company undertakes to ensure that each Participating Individual named by it complies with the obligations under paragraphs 1 and 2 as well as under § 14 (3) and (4). It is responsible for the fault of these persons pursuant to § 278 BGB to the same extent as for its own fault. Before the AI working environment is first used, the Company shall provide each named Participating Individual with the privacy notice for participating individuals supplied by the Johner Institute.

15.4 If the Company or a Participating Individual named by it breaches the obligations under paragraph 1 or paragraph 2, the Company shall indemnify the Johner Institute against the claims which third parties assert against the Johner Institute arising from or in connection with that breach, including the reasonable costs of legal defence. This covers in particular amounts which the Johner Institute has to pay on the basis of its own indemnification obligation towards the provider. This indemnification does not apply,

- a) to the extent the claim is based on a breach of duty by the Johner Institute, on intent or gross negligence of the Johner Institute, or on a breach of § 14 (6),
- b) to the extent the claim is based on content which the Johner Institute itself provided, in particular on the sample product and the program material, or on the service and its outputs, and
- c) to the extent the Johner Institute has breached the Company's participation rights under paragraph 6 although their exercise was possible.

15.5 The claims of the Johner Institute under paragraph 4 are limited, per contract in total, to three times the remuneration paid for the contract concerned. The limitation does not apply to the extent the Company or a Participating Individual named by it acted intentionally. The Johner Institute's own indemnification obligation towards the provider is not limited in amount. The Johner Institute itself bears the portion exceeding the above maximum amount.

15.6 The Company shall notify the Johner Institute without undue delay as soon as it becomes aware of circumstances which may trigger a claim under paragraph 4. The Johner Institute 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 the Johner Institute, to the extent this corresponds to its obligations towards the provider. In doing so, the Johner Institute will give reasonable consideration to the Company's interests. If a party breaches its duty to notify or to cooperate and the legal defence is

thereby substantially impaired, the obligations of the respective other party lapse to the extent thereby caused.

15.7 The Johner Institute makes the settings pursuant to § 14 (6) and does not consent to use of the entered content for training purposes. No assurance is given as to the provider's actual conduct, as to processing exclusively within the European Union, or as to no data being stored at all. There is no EU data residency for the service used. The Johner Institute takes no knowledge of the entered content and therefore cannot give any assurance that no personal data is entered. The Participating Individual is obliged to ensure this pursuant to paragraph 2. Details of the data processing follow from the privacy notice for participating individuals.

15.8 The liability cap under § 12 (4) concerns exclusively claims of the Company against the Johner Institute. It does not limit the claims of the Johner Institute under paragraph 4. Paragraph 5 applies to those. These paragraphs establish exclusively an allocation in the internal relationship. Claims of third parties and measures by supervisory authorities against the Johner Institute, the Company or the Participating Individual remain unaffected, and the Johner Institute cannot invoke this internal allocation vis-à-vis third parties.

§ 16 Packages for several persons

16.1 The contracting party of the Johner Institute is the booking Customer. At the time of the order, or at the latest before the start of the program, the Customer names to the Johner Institute the participating natural persons with their names and business email addresses.

16.2 The access credentials of the individual participants are personal and non-transferable. § 4 (2) and (3) as well as § 14 (4) apply accordingly to each named person.

16.3 If a named person leaves the Customer during the program term, the Customer is entitled to name a replacement person once per person. The Customer ensures that the departing person has no further access to program content and access credentials, and notifies the Johner Institute of the departure without undue delay.

16.4 Distribution of the places among different companies or third parties outside the group is excluded. The same applies to the accesses to the AI working environment.

§ 17 Data protection

17.1 The Johner Institute processes the Participant's personal data for the performance of the contract pursuant to Art. 6 (1) lit. b GDPR. Details follow from the privacy policy at www.johner-institut.de/datenschutz. For personal data of the Participating Individuals, the privacy notice for participating individuals pursuant to § 15 (3) applies with priority.

17.2 Art. 6 (1) lit. b GDPR (performance of the contract) applies to the recording of live sessions, as the provision of recordings is part of the contract. § 8 remains unaffected.

§ 18 Final provisions

18.1 Unless these Special Terms and Conditions provide otherwise, the General Terms and Conditions of Johner Institut GmbH apply in addition.

18.2 German law applies exclusively to legal disputes arising from or in connection with this contract, 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 place of jurisdiction for legal disputes arising from or in connection with this contract is exclusively Konstanz.

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

18.5 Should a provision of this contract be or become invalid, the legal validity of the remaining provisions remains unaffected.