

TERMS AND CONDITIONS – AZ BIOTECH CONSULTING

Article 1 – Definitions

In these Terms and Conditions, the following words, whether used in the singular or plural, shall have the meanings set out below:

- 1.1. **AZ Biotech Consulting:** the company providing the Services and Products, represented by AZ Biotech Consulting SRL/BV, or any legal successor.
- 1.2. **Client:** any natural or legal person entering into an Agreement with AZ Biotech Consulting.
- 1.3. **Agreement:** the Proposal, these Terms and Conditions, and any written amendment or purchase order accepted by both Parties.
- 1.4. **Services:** all activities provided by AZ Biotech Consulting, including scientific, quality and regulatory support; ISO 13485 and QMS consulting; IVDR/MDR support; audits; documentation review; certification preparation; regulatory solutions; training and coaching.
- 1.5. **Products:** ready-to-use QMS software applications provided by AZ Biotech Consulting, such as **QMS ReadySet**, intended to be installed or used on Third-Party Platforms (e.g. Atlassian Confluence).
- 1.6. **Deliverables:** any document, report, analysis, matrix, template, presentation or other output supplied to the Client as part of the Services.
- 1.7. **License:** the limited, non-exclusive and non-transferable right granted by AZ Biotech Consulting to the Client to use the Products in accordance with the Agreement.
- 1.8. **Third-Party Platform:** any software or hosting environment provided by a third party (e.g. Atlassian Confluence) required to operate the Products.
- 1.9. **Confidential Information:** all non-public information exchanged between the Parties, whether orally or in writing.
- 1.10. **Parties:** AZ Biotech Consulting and the Client.

Article 2 – Purpose of the Agreement

2.1. These Terms and Conditions define the rights and obligations of the Parties regarding:

- the provision of **Services**; and
- the sale of **Products**, including ready-to-use QMS software applications provided under perpetual Licenses.

2.2. All Services and Products are subject to a Proposal or quotation accepted by the Client.

2.3. These Terms and Conditions prevail over any terms of the Client unless expressly agreed in writing by AZ Biotech Consulting.

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Article 3 – Provision of Services

3.1. AZ Biotech Consulting shall deliver the Services with due care and professionalism in accordance with industry best practices.

3.2. Services constitute an **obligation of means**, not an obligation of result.

3.3. The Client shall provide all information, access, data and resources required for proper performance of the Services.

3.4. Timeframes indicated are for information purposes only unless expressly guaranteed in writing.

Article 4 – Intellectual Property

4.1. AZ Biotech Consulting retains full ownership of all intellectual property rights related to its methodologies, templates, tools, analyses, Deliverables, and the Products and their associated documentation, structure and content.

4.2. The sale of a Product does **not** transfer any intellectual property rights. The Client receives only a License as described in the Agreement.

4.3. Unless otherwise specified, the License is:

- **perpetual**,
- **non-exclusive**,
- **non-transferable**,
- restricted to **internal use** by the Client and, if applicable, to the legal entities explicitly identified in the Proposal.

4.4. The Client is strictly prohibited from:

- distributing, sublicensing, selling, renting, leasing, lending or otherwise making the Products available to any third party;
- using the Products to provide commercial services to third parties (consulting, SaaS, documentation platforms, outsourced QMS, etc.);
- massively exporting or reusing the structure or content of the Products to develop a competing or equivalent offering;
- removing or modifying any copyright, proprietary notice, branding or watermark;
- reverse engineering, decompiling or disassembling the Products, except as expressly permitted by mandatory law.

4.5. The Client may create backup copies solely for internal use, subject to appropriate security measures preventing unauthorized access.

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Article 5 – Confidentiality

- 5.1. Each Party shall protect the Confidential Information of the other Party.
- 5.2. Confidential Information shall be used only for performing the Agreement.
- 5.3. This obligation remains in force for **five (5) years** after termination of the Agreement.
- 5.4. Exceptions apply to information that is public, previously known, lawfully obtained from a third party, or required by law to be disclosed.
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Article 6 – Liability

- 6.1. Services and Products are provided “**as is**” based on available information and on the Client’s environment.
- 6.2. AZ Biotech Consulting shall not be liable for:
- incorrect configuration or misuse of the Products by the Client;
 - any regulatory, certification or audit outcome;
 - data loss, corruption or security issues arising from the Client’s systems or Third-Party Platforms.
- 6.3. No warranty is provided regarding:
- the absence of defects or software errors;
 - successful ISO certification or regulatory approval;
 - compatibility with future versions of Third-Party Platforms, unless otherwise agreed.
- 6.4. The total liability of AZ Biotech Consulting, for all claims combined, is limited to the **amount paid by the Client** for the specific Service or Product giving rise to the claim.
- 6.5. AZ Biotech Consulting shall never be liable for indirect or consequential damages such as lost revenue, lost data, lost opportunity, business interruption, or reputational damage.
- 6.6. These limitations do not apply in case of proven willful misconduct or gross negligence by AZ Biotech Consulting.
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Article 7 – Pricing and Payment Terms

- 7.1. Services are billed according to the Proposal (fixed price, time and materials, or daily rate).
- 7.2. Products (QMS ReadySet perpetual Licenses) are billed as a **one-time fee**, unless additional maintenance or support is subscribed separately.

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7.3. Invoices are payable within **30 calendar days** from the invoice date.

7.4. Late payments automatically incur:

- legal interest rate + 5%, and
- a lump-sum compensation of 10% of the unpaid amount (minimum €50).

7.5. Additional expenses (travel, platform fees, third-party services) may be charged separately with prior agreement.

Article 8 – Duration and Termination

8.1. Service-related Agreements last for the period defined in the Proposal.

8.2. Unless otherwise agreed, the License on the Products is **perpetual** and may end only in the following situations:

- material breach by the Client;
- mutual agreement between the Parties;
- bankruptcy or dissolution of the Client.

8.3. Either Party may terminate the Agreement for material breach not remedied within **30 days** after written notice.

8.4. Upon termination:

- completed work remains due;
- late cancellations of scheduled work may be billed as specified in the Proposal.

8.5. For License violations, AZ Biotech Consulting may:

- immediately suspend or terminate the License;
- require destruction of all copies;
- request written confirmation of such destruction.

8.6. Confidentiality and intellectual property provisions survive termination.

Article 9 – Data Protection

9.1. AZ Biotech Consulting processes personal data in compliance with the GDPR (EU 2016/679).

9.2. Data is processed solely for executing the Agreement.

9.3. If necessary, the Parties may conclude a Data Processing Agreement.

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Article 10 – Force Majeure

10.1. Neither Party shall be liable for failures caused by force majeure events (natural disasters, pandemics, war, strikes, major IT outages, prolonged unavailability of Third-Party Platforms, etc.).

10.2. If force majeure lasts longer than **60 days**, each Party may terminate the Agreement without compensation, except for Services already performed.

Article 11 – Third-Party Platforms and Technical Environment

11.1. Some Products require Third-Party Platforms such as Atlassian Confluence. The Client is solely responsible for:

- subscribing to such platforms;
- paying related fees;
- complying with the third-party terms of use;
- ensuring the availability, performance and security of its environment.

11.2. AZ Biotech Consulting is not responsible for any malfunction, interruption, update or change in the terms of use of a Third-Party Platform.

11.3. Compatibility is guaranteed only for platform versions specified at the time of delivery. No guarantee is given for future or obsolete versions unless expressly agreed.

Article 12 – Support, Maintenance and Updates

12.1. Unless explicitly included in the Proposal, the perpetual License does **not** include:

- updates,
- upgrades,
- support,
- maintenance,
- or content updates to the QMS templates.

12.2. Support and maintenance may be provided under a separate contract or subscription.

12.3. AZ Biotech Consulting may offer new versions or modules as paid updates or new Licenses.

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Article 13 – Specific Provisions for QMS ReadySet Software

13.1. Products include ready-to-use QMS software applications such as QMS ReadySet, designed for use on one or more Third-Party Platforms specified in the Proposal.

13.2. The License is granted for:

- the specific environment(s) (e.g. a designated Confluence instance) specified in the Proposal;
- the specified perimeter (e.g. one legal entity, one site, or a defined number of users).

13.3. Any extension of the perimeter (additional users, sites, legal entities, new environment, migration to a new instance) requires a new License or an amendment and additional fees.

13.4. The License authorizes the Client to:

- view, use and operate the QMS ReadySet content;
- adapt the content for internal use only.

13.5. The License does **not** permit:

- duplication of the Product for other clients, affiliates or partners not included in the Agreement;
- commercial reuse or redistribution;
- mass extraction of content to build competing solutions;
- sharing the Product with external consultants unless explicitly authorized.

13.6. In case of suspected breach, AZ Biotech Consulting may conduct a **usage audit**, based on logs, instance configuration, and relevant data. The Client shall cooperate in good faith.

13.7. In case of unauthorized use, AZ Biotech Consulting may:

- require regularization (purchase of missing Licenses);
- charge compensatory fees up to **three (3) times** the catalog price per unauthorized user/entity/environment;
- suspend or terminate the License with immediate effect.

Article 14 – Miscellaneous

14.1. The Client may not transfer or assign the Agreement or the License without prior written approval from AZ Biotech Consulting.

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14.2. If any provision is found invalid, the remaining provisions shall remain fully enforceable.

14.3. Failure or delay in exercising a right shall not constitute a waiver of that right.

Article 15 – Governing Law and Jurisdiction

15.1. These Terms and Conditions are governed by **Belgian law**.

15.2. Any dispute relating to the validity, interpretation or performance of these Terms and Conditions shall be submitted to the **courts having jurisdiction over the registered office of AZ Biotech Consulting**, unless amicable resolution is achieved.

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