

GENERAL TERMS AND CONDITIONS OF SERVICES

of RegIntA GmbH

1. Scope of Application

- 1.1. These General Terms and Conditions of Services (hereinafter referred to as "GTC") apply to any contractual agreements between RegIntA GmbH (hereinafter referred "RegIntA") and its customer (hereinafter referred to as "Client") on the services set out below. Deviating or additional terms and conditions of the Client do not apply.
- 1.2. The services provided by RegIntA based on these GTC are only offered to entrepreneurs in terms of section 14 of the German Civil Code, legal entities under public law and special funds under public law.

2. Scope of Services

- 2.1. RegIntA has developed a validated database to help the pharmaceutical and medical device industry to comply with the specific regulatory requirements for medical devices and medicinal products. The services offered by RegIntA are provided in English via a validated database of RegIntA (hereinafter "Database").
- 2.2. The information provided by RegIntA is restricted on the perspective of the pharmaceutical or medical device industry. It will not include information on potential reporting obligations of other stakeholders such as, namely but not exclusively, distributors or investigators.
- 2.3. Within the Database, RegIntA shall provide regularly updated regulatory intelligence for general requirements based on country specific legislations. The client is solely responsible to comply with obligations as defined in the provided requirements.
- 2.4. In some situations, the actual regulatory requirements of Client might deviate from the general regulatory requirements provided by the Database, for example due to the specifics of a clinical trial or a marketing authorization of the client. If Client requires assistance in determining whether such specific regulatory requirements apply, the Parties will negotiate a potential separate consultancy agreement.
- 2.5. For some countries or in certain situations regulatory requirements may not be defined or may not be identifiable in legal documents or on official websites. Client accepts that, in these situations and if possible, RegIntA shall provide general requirements based on international guidelines, as long as this is clearly highlighted in the provided information.

3. Conclusion of Contract / Projects / Work Orders

- 3.1. Services by RegIntA shall be provided on a project level ("Projects"). For each of the Projects RegIntA shall provide project-related regulatory intelligence via the Database.
- 3.2. Each Project shall be defined in a work order ("Work Order") characterized by the specifics of the information sought by Client, namely dependent on
 - a. the product type (medical device or medicinal product)
 - b. the scenario (registration, safety reporting for clinical trials, post market surveillance, etc.)
 - c. the country for which information shall be obtained.

Any Work Orders shall be governed by these GTC.

- 3.3. Any Work Order placed by the Client via the electronic client system of RegIntA ("Electronic Client System") is considered a binding offer which can be accepted by RegIntA. RegIntA will communicate such acceptance by e-mail via the Electronic Client System.
- 3.4. Section 312i (1) sentence 1 numbers 1-3 of the German Civil Code shall not apply.

4. Service Levels

The regulatory information provided by RegIntA is offered in three different packages as further described in **Annex 1** to these GTC with the following service levels.

- a. The "Basic" package provides an up-to-date summary of the main regulatory provisions (basic overview with assessment).
- b. The "Premium" package gives the Client a detailed insight into the regulatory provisions.
- c. The "Premium Plus" package comprises all the details and instructions required to meet the regulatory obligations.

5. Obligations of RegIntA

- 5.1. Client shall be granted access to RegIntA's online database for Projects in accordance with these GTC, the specifics of its Work Orders and the chosen service level in terms of Section 4.
- 5.2. Access is granted based on personalized accounts. Any person who shall have access to the regulatory intelligence provided by RegIntA ("Users") will be granted an individual account based on the placement of an order via the electronic client system of RegIntA. For each account, RegIntA shall submit individual login data to the respective User designated by Client. The Client determines the Projects to which the User has access. Upon request of the Client, the User is given full access to all of the Client's Projects. An overview of all accounts shall be available via the Electronic Client System.

- 5.3. RegIntA will check the contracted regulatory intelligence on a weekly basis to ensure it is up to date. Based on those checks, RegIntA will include necessary changes to the database within 10 business days after the performed check. The regulatory information provided shall be version-controlled. RegIntA will inform Users about updates of regulatory intelligence via notifications posted on the online database. If requested, the User will also receive e-mail notification. Relevant changes compared to the previous version are highlighted in the database.
 - 5.4. If an audit is conducted at the Client's premises and details of RegIntA's services are required, an audit trail will be prepared by RegIntA on request by Client. The audit trail shall be based on samples and will be restricted to time periods RegIntA was contractually obliged to provide the queried data to Client. The audit trail must be requested by Client in writing at least 5 business days before the planned audit. The written request will include at least the following information for one sample: Product type, area, the country concerned and the date required. For each single sample RegIntA shall receive additional compensation of 100 € paid for by Client and subject to these GTC.
6. Training / Support
- 6.1. If requested by Client within four weeks after the acceptance of the first Work Order, RegIntA shall conduct one webinar as Database induction training. Further trainings shall not fall within the scope of this contract; such additional services are available subject to the formation and provisions of a separate training contract.
 - 6.2. An English and German Database manual will be available online.
 - 6.3. Individual support, via telephone and email, regarding the content of the Database and technical questions is granted in German or English language during the regular business hours of RegIntA, Altenstadt, Germany.
7. Obligations of Client
- 7.1. Except for the trial offer period pursuant to Section 12, the Client shall pay as consideration for the services granted by RegIntA a service fee ("Service Fee") in accordance with the Work Orders and account details established and provided via the Electronic Client System. The Service Fee is calculated as the sum of the costs for the booked individual accounts and the cumulated costs for all Projects defined in Work Orders.
 - 7.2. The access granted for Projects is restricted to Users as defined by the accounts booked and listed in the Electronic Client System. Client and Users must not pass on provided login data to other persons, either within or outside Client's legal entity. Client will instruct Users accordingly.

7.3. If login details or regulatory intelligence provided by RegIntA are passed on to individuals or parties not booked and registered as users in the Electronic Client System, RegIntA is entitled to a fair and adequate compensation, unless the Client can prove the unauthorized access was caused neither by his negligence or intent; for this purpose, negligence and intent of the Users will be legally attributed to the Client. To determine a fair and adequate compensation, the mode of calculation for service fees in Work Orders between the Parties shall be considered. Any further claims and rights to which RegIntA is legally entitled on the basis of a scenario as defined in the first sentence of this paragraph shall remain unaffected.

8. Terms of Payment

8.1. All service fees agreed upon shall be considered net prices unless explicitly stated otherwise. Value added tax (VAT) will be added to the net service fee in accordance with applicable law in its relevant applicable version.

8.2. Invoices will be in Euro. All payments to RegIntA shall be in Euro.

8.3. For services rendered based on Work Orders, RegIntA will issue a monthly invoice to Client. Client will pay such invoices within 10 days after receipt.

8.4. Payments shall be made to the following bank account:

Account Owner:	RegIntA GmbH
IBAN:	DE60506616390004142926
BIC:	GENODEF1LSR
BANK:	VR Bank Main-Kinzig-Büdingen

9. Insurance / Liability

9.1. In cases of pecuniary damages or damages to property caused by ordinary negligence, RegIntA's liability is restricted to breaches of essential contractual duties and limited to damages that were foreseeable when the contract was concluded and typical of this type of agreement.

9.2. As regards of the foreseeable damages mentioned in 9.1, RegIntA will obtain and maintain a business liability insurance with sufficient coverage of 2 Mio. € for pecuniary damages of Client resulting from wrongful acts or omissions by RegIntA. If Client is interested in an insurance beyond the scope of the aforementioned coverage a supplementary insurance is possible on Client's request if insurance premiums incurred thereby will be paid for by Client.

9.3. Upon request, RegIntA will provide Client with a copy of RegIntA's insurance policy.

10. Term

- 10.1. Work Orders without a defined termination date for services shall remain in effect for one year after the start date provided in the Work Order. They shall automatically renew for additional one-year periods, unless terminated pursuant to Section 11.
- 10.2. Work Orders with a defined termination date for services shall remain in effect for the period defined by the start date and end date of the services as specified in the relevant Work Order, unless terminated pursuant to Section 11.
- 10.3. The booking of user accounts shall be effective upon the acceptance of the Client's order by RegIntA. User accounts are always made available at the beginning of a calendar month, starting with the calendar month after the booking was accepted, unless the booking request was placed less than five calendar days before the end of a calendar month. In the latter case, the user account is made available one month later, at the beginning of the corresponding calendar month. RegIntA will communicate its acceptance of the booking request and the availability date of the user account via the Electronic Client System.
- 10.4. User accounts are booked on a monthly basis. The booked user account is automatically renewed at the start of a new calendar month for an additional calendar month, unless terminated pursuant to Section 11.
11. Termination
 - 11.1. Work Orders without a termination date for services can be terminated by 3 months' notice prior to the renewal date as defined in clause 10.1.
 - 11.2. Work Orders with a defined termination date for services can be previously terminated by 3 months' notice towards the end of the first year or, afterwards, by 3 months' notice towards the end of each full year of service as determined by the start date provided in the Work Order.
 - 11.3. Booked user accounts can be terminated with a notice period of 10 business days prior to the renewal date as defined in 10.4.
 - 11.4. The termination of one or several Work Orders has no effect on other Work Orders. The termination of one or several user accounts has no effect on other user accounts.
 - 11.5. Terminations have to be declared either in written form or via the Electronic Client System.
 - 11.6. Should either Party file or have filed against it a petition in bankruptcy or institute any proceedings for liquidation or winding up; then the other Party may, in addition to other rights and remedies it may have, terminate Work Orders and user accounts by written notice. Such termination(s) will be effective immediately.
 - 11.7. The following Sections of these GTC shall survive termination or expiration of any Work Order: 7.2, 7.3 (Passing on of login details); 9 (Insurance / Liability); 11.7 (Survival); 13 (Confidentiality); 14 (Governing Law / Jurisdiction); 15 (Miscellaneous).

- 11.8. The right of extraordinary termination for good cause shall remain unaffected by the above provisions.

12. Trial Offer

- 12.1. RegIntA offers the Client access to regulatory intelligence for 3 countries for 3 months for free (Trial Offer). The Client shall be free to choose a service level pursuant to Section 4 for each of the three countries.
- 12.2. The Trial Offer is limited to one User access per Client.
- 12.3. **The Client shall be entitled to terminate the Trial Offer in accordance with Section 11.5 at least 2 weeks before the end of the 3-months period either fully or partially with regard to single countries. Unless the Client gives notice of termination within the afore-mentioned period, the Trial Offer will be converted into separate Work Orders for each country which are subject to a Service Fee according to Section 7.1. Such Work Orders shall remain in effect for one year after the end of the 3 months for free period of the Trial Offer and shall be renewed for additional one-year-periods pursuant to Section 10.1 unless terminated pursuant to Section 11.1.**
- 12.4. Upon conversion of the Trial Offer into a chargeable Work Order the Client shall be entitled to request a change of the selected country or service level. Otherwise the Work Orders shall apply to the countries and service levels chosen by the Client for the Trial Offer.

13. Confidentiality

- 13.1. The Parties acknowledge that any oral or written information exchanged among them, specifically but not exclusively login details and regulatory intelligence with respect to the services referred to in these GTC, is confidential information.
- 13.2. Each Party shall maintain the confidentiality of all such information, and without obtaining the written consent of the other Party, it shall not disclose any relevant information to any third parties, except in the following circumstances:
- a. such information is in the public domain at the time of disclosure;
 - b. information disclosed as required by authorities or applicable laws or
 - c. information required to be disclosed by any Party to its legal counsel or financial advisor, if such legal counsel or financial advisor is also bound by confidentiality duties similar to the duties in this section.
- 13.3. Regarding this confidentiality clause, the use of service providers, like email service providers, telecommunications service providers, etc., for general business purposes shall not be regarded as a disclosure of confidential information to them.

- 13.4. Disclosure of any confidential information by the staff members or agency hired by any Party shall be deemed disclosure of such confidential information by such Party, which Party shall be held liable for breach of this confidentiality obligation.
- 13.5. In addition to the aforementioned paragraphs, for login data and regulatory intelligence provided as a service by RegIntA the stricter rules of Section 7 of these GTC (“Obligations of Client”) do apply.

14. Governing Law / Jurisdiction
 - 14.1. Exclusive place of venue for any disputes arising out of or relating to the contractual relationships between the parties shall be the competent court for RegIntA’s place of residence (Altenstadt, Germany).
 - 14.2. Any contractual relationships between the parties shall be construed in accordance with and governed by the substantial laws of Germany without regard of the conflict of laws provisions thereof.

15. Miscellaneous
 - 15.1. In the event, that any provisions of these GTC are invalid or unenforceable, the other provisions shall remain in full force and effect without said provision. The invalid or unenforceable provision shall be replaced by the statutory provisions.
 - 15.2. These GTC and the accepted Work Orders established and provided via the Electronic Client System, sets forth the entire agreement and understanding of the parties with respect to the subject matter hereof, and supersedes all prior discussions, agreements and writings relating thereto.

ANNEX 1

Choose the package that fits your needs			
	Basic	Premium	Premium plus
Basic overview with assessment	✓	✓	✓
General information incl. legal basis	-	✓	✓
Registration parties	-	✓	✓
Risk classification	-	✓	✓
Submission process	-	✓	✓
Format & content of application	-	✓	✓
Validity & renewal	-	-	✓
Change notification	-	-	✓
Facility registration	-	-	✓
Labelling	-	-	✓
Forms & Instruction for download	-	-	✓

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