



ND Pharma & Biotech

Making Life Better

Quality and Value
Delivered
Worldwide



Pharmaceutical compounding

In Pharmaceutical Compounding Sourcing and Supply as in any other field we operate, our compromise to meet our client's needs and expectations is clearly defined in our proposition: **Quality and Value Delivered Worldwide.**

It is a shared ideal that inspires, drives and motivates us. For you this means a compromise with the excellence, a commitment with Research, Development, Service and Skilled Work that will deliver real and unparalleled results with unrivalled added value to your process, products and brands thru our being.

An aerial night view of a city, likely London, showing the River Thames and numerous illuminated buildings. A large yellow circle is overlaid on the image, containing text. The background is a vibrant sunset or sunrise sky with orange and blue hues.

Our global reach and trans-continental operations and capacities means we can deliver innovative, customized commercial and compliance solutions everywhere you do business.

An aerial night view of London, showing the River Thames, the London Bridge, and St. Paul's Cathedral. The city lights are visible, and the sky is a mix of blue and purple.

Globalization is changing the world, opening up opportunities, new markets and sources of supply but also increasing competition.

There is continuous pressure to shorten production cycles and control costs to maintain competitive advantage, and this demand companies accepting those challenges and improvement systems in a total quality environment.

At same time, your obligations have never been greater. Every aspect of your business is under the spotlight and every new market and regulatory change brings new rules and requirements than make to run a business some kind of a nightmare.

Your sustainability performance is an increasingly important factor when doing business, influencing the future continuity and success of your businesses, companies, transactions, development and growth.

With ND Pharma & Biotech Co. as your partner, you can pursue your business goals in the confidence that all quality and safety aspects of your products and processes are taken care of.

Our services can help you to focus on what matters most to you - growing revenues, increasing market share and achieving greater business success.

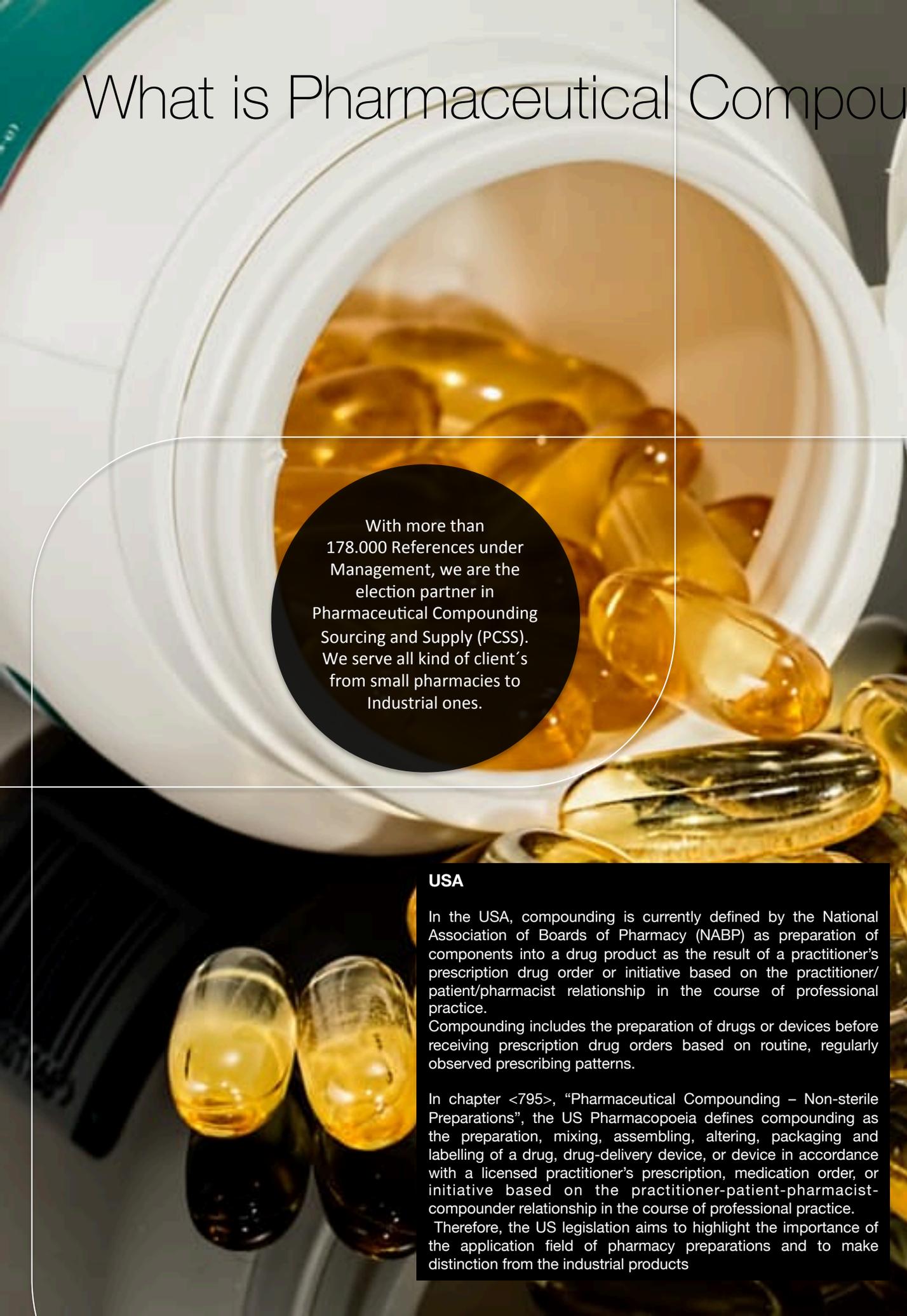
You can also be certain that your reputation is in safe hands. Our in-depth and far-reaching expertise brings assurance to manufacturing and operations for hundreds of companies and millions of consumers worldwide every day.

Our global reach and trans-continental operations and capacities means we can deliver innovative, customized commercial and compliance solutions everywhere you do business, not just today but in the future as well.

In a world that is constantly changing, it is reassuring to know that professional and expert support is always available, whenever and wherever you need it

ND Pharma & Biotech Co. is proudly operating in 5 continents thru a complete, professional and well-structured network of agents, representatives, distributors and partners.

What is Pharmaceutical Compounding



With more than 178.000 References under Management, we are the election partner in Pharmaceutical Compounding Sourcing and Supply (PCSS). We serve all kind of client's from small pharmacies to Industrial ones.

USA

In the USA, compounding is currently defined by the National Association of Boards of Pharmacy (NABP) as preparation of components into a drug product as the result of a practitioner's prescription drug order or initiative based on the practitioner/patient/pharmacist relationship in the course of professional practice.

Compounding includes the preparation of drugs or devices before receiving prescription drug orders based on routine, regularly observed prescribing patterns.

In chapter <795>, "Pharmaceutical Compounding – Non-sterile Preparations", the US Pharmacopoeia defines compounding as the preparation, mixing, assembling, altering, packaging and labelling of a drug, drug-delivery device, or device in accordance with a licensed practitioner's prescription, medication order, or initiative based on the practitioner-patient-pharmacist-compounder relationship in the course of professional practice.

Therefore, the US legislation aims to highlight the importance of the application field of pharmacy preparations and to make distinction from the industrial products



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What is Pharmaceutical Compounding?

EUROPE

The preparation of medicinal products in pharmacies are not harmonized all over Europe; there are only some common definitions. Compounding activity rather falls under the national competencies of individual European countries. The first European directive of medicinal product was introduced in the 1965, but the compounding activity of the pharmacies was not considered. This concept was introduced with the Directive 89/341/CE that amended Directive 65/65/CE.

Here was defined:

Magisterial formula: any medicinal product prepared in a pharmacy in accordance with a prescription for an individual patient.

Officinal formula: any medicinal product which is prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia and is intended to be supplied directly to the patients served by the pharmacy in question.

These definitions are repeated in the Directive 2001/83/CE, which is still in force. This directive exempts “pharmaceutical preparations” from the industrial procedures, such as manufacturing and marketing authorizations. This approach has been recently confirmed by the European Pharmacopoeia monograph on “pharmaceutical preparations”: they are defined as medicinal products generally consisting of active substances that may be combined with excipients, formulated into a dosage form suitable for the intended use, where necessary after reconstitution, presented in a suitable and appropriately labeled container.

Pharmaceutical preparations may be licensed by the competent authority or unlicensed and compounded to meet the specific need of a patient according to current legislation.

They are distinguished in two categories:

Extemporaneous preparations (according to Directives 65/65/CE: magisterial formula), i.e. pharmaceutical preparations individually prepared for a specific patient or patient group, supplied after preparation;

Stock preparations, i.e. pharmaceutical preparations prepared in advance and stored until a request for a supply is received.

Following this definition, in some European countries it is allowed to prepare in stock other than officinal formulas also magisterial formulas, in order to have an immediate availability of the product for the next dispensation.

ND Pharma & Biotech Co. is ready-to-serve this important segment within the same standards of professionalism and excellence we apply to all our business sector operations both commercial and distribution.



Pharmaceutical Compound

We are a biopharmaceutical and biotechnological company, with a solid scientific medical and biochemical foundation, and strong tradition and experience in different fields from the cosmetic and beauty to New Drug discovery. We serve also Veterinary, Animal Nutrition, Agrochemicals, Industrial and Construction business. Pharmaceutical Compounding Sourcing and Supply is another important segment within our business policy and growth strategy.

As science is part of our reason to exist, the foundation of every development and the light that shines after each development we made is related to the development of products and services that may help in some ways to make our lives better.

Chemistry and the provision of Chemicals, no matter if there are API's, Biochemicals, Analytical Reagents, Raw Materials, Starters, Intermediates or any other, is a strong demanding and time consuming task. From manufacturing and/or globally sourcing to plant auditing, re-processing, adjusting and analysis to fit our client's exigencies to store, classification, controlling, packaging, compliance, registration, Health & Safety issues and delivering worldwide.

This is why we want to let you to know the immense effort and continuing improvement that our people is making every day to reach that level of excellence and professionalism in the provision of goods and services, with the best quality available at the most affordable price, not forgiving all the issues surrounding this activities.

But our work is of capital importance when we supply hundreds of client companies worldwide that are using our products in their own ones. So with this in mind, we encourage to all our partners, employees and associates to pursue the safes and more sustainable chemicals we are able to find, manufacture, process and serve, ensuring the tranquility of all those who trust on our Company.

The ND Pharma & Biotech Co.



The context of a changing market

As Sourcing and supply costs continue to rise and the pathway to regulatory approval becomes more difficult, time-to-market has become a critical factor. Pharmaceutical Compounding Sourcing and supply has never become more critical to serve this important sector in population's personalized healthcare and treatment and Hospital attention to certain conditions and diseases in medications shortages, special situations and disease.

The quality we bring

We can assist your R&D and Substance Manufacturing needs and efforts and help you to meet specific requirements for the development and manufacture of officinal preparations and magister formulae, as well as specific required ordered drugs from Physicians, Hospital Pharmacists and Profession colleagues or even the General Public "on demand" or "by prescription". We support every phase of the process, from sourcing, manufacturing, testing or purification right up to the packaging and delivery of demanded ingredients, raw materials, chemicals, active substances and principles or finished products. Our expertise ranges from analytical testing programs and bio analysis of drug-intended products.

Our value in practice - decisive intervention

We serve the Big Pharma, Biotech industry, Industrial Chemicals, Food & Nutrition Sector, Nutraceuticals, Nutricosmetics, Cosmetic, Agrochemical and Performance Materials field since we have a broad portfolio of references under management (+178.000 and growing), having our products present during the different stages of a production process.

Pharmaceutical Compounding is another important sector we serve, with more than 200.000 potential clients just in EU and the USA.

ND Pharma reputation for troubleshooting led them to contact us immediately. Our team worked around the clock with the client to evaluate the issue and provide solutions delivering it worldwide. Ultimately, our work ensured that drug/substance manufacture could continue on schedule - avoiding the significantly greater costs of delayed production, scarcity of materials, unnecessary costs and failure to provision.

Our value in practice – international insight

Our regulatory knowledge and understanding are also highly valued by the world's largest manufacturers to the smallest pharmacy in recondite corners of the planet both in need of solutions as well. To help our clients, no matter the size and needs to navigate the labyrinth of sourcing, accessing to products and regulatory standards that apply to their products is what makes sense to our existence. Our clients build and maintain a reputation relying on our commitment with excellence that for sure will be helping them to grow and getting our client's customers satisfied.

- Iodinated Products
- Linkers
- Naphthalenes
- Oxazoles
- Peptide Reagents
- Phenols
- Linkers
- Naphthalenes
- Oxazoles
- Peptide Reagents
- Phenols
- Picolines
- Piperazines
- Pyrans
- Pyrazines
- Pyrazoles
- Pyridines
- Pyrimidines
- Pyrroles
- Quaternary Ammonium salts
- Quinines
- Quinolines
- Research Organics & Inorganics
- Stains & Indicators
- Sugars
- Tetralones
- Tetrazoles
- Thiadiazoles
- Thiazoles
- Thiophenes
- Triazines
- Triazoles
- Water Analysis



Chemicals for R+D and Substances Manufacturing

To be competitive today, your production processes must be lean and efficient without cutting corners on safety, no matter if you're producing artisan preparations in the back office of your Pharmacy to large quantities in a modern premises serving Hospitals and other organizations form a well-structured industrial Pharmacy. The pressure to use the most environment-friendly chemicals, API's and cost-effective/cost-competitive compounds at the same time that those should to be safe to humans, is enormous today.

The quality we bring

With expertise in every area from R+D to Manufacturing of Preparations and Substances to Distribution, we can help you to adapt your value chain and compliance programs to this ever-changing and ever-evolving environment. Our outsourcing solutions can assist you in managing your cost base and help you to enhance innovation as well. Experienced and highly qualified professionals, scientists and engineers who can provide rapid and sound authoritative answers to your needs are staffing our chemical testing laboratories, for your tranquility.

Our value in practice – the perfect ingredients

With thousands of manufacturers and suppliers dispersed across the globe, it is a major operation for Pharmacists and companies involved in Pharmaceutical Compounding companies to conduct regular on-site quality and materials safety audits. The Management of multiple providers brings its own challenges as well. Our clients wanted to outsource this responsibility to a single supplier that could provide global consistency of method and reporting as well as deliver all the benefits that a Sourcing and supply can bring to your business through economies of scale without suffering the overcharge of operative costs.

Our clients also wanted to minimize any disruption to their day-to-day operations. Having worked extensively with ND Pharma over the years, this intimate relationship let them to improve the traceability, transparency and sustainability of their production chain, as our clients know that they could trust us to deliver. They also recognized the value of our industry focus and the vocational service and the possibility of having our products delivered worldwide.

Our local teams worked closely with suppliers in each location to review their operations and advise any corrective action required. We have raised the compliance level up to the required standard at each point in our client's global supply chain. Our sole supplier model has also delivered on expectations of substantial operational cost savings.

So in that way, we can support our policy established within our principal operational service sustainment concept: We give our client's service **From Milligrams to Tons.**

General Terms and Conditions of Sale (Pharmaceutical Compounding)

SELLER

ND Pharma & Biotech

(Acting on own name and representation and/or or through any of the associated companies, subsidiaries, and/or licensees)

Valid from October 2016.

BUYER

Any Company, business form, trader, sole trader, corporation, agent, distributor or qualified person (physical and/or juridical), that place a PO (Purchase Order) to ND Pharma & Biotech, its affiliates, subsidiaries or licensed vendors, in any form, by phone, e-mail, physically, electronically, or by any other acceptable means. Orders are accepted when SELLER issues a PFI (Pro Forma Invoice), Invoice, PO confirmation and any other form of valid document that means an acceptance of the PO by SELLER.

ACCEPTANCE & VARIATIONS OF CONDITIONS

All sales by the Seller are subject to and expressly made upon the terms and conditions contained herein. No variation of these terms and conditions will be valid unless agreed to in writing and signed by an authorized representative of the Seller. Order of products, purchase orders and any other form of acquisition of products mean an implicit acceptance of all this conditions and terms, without exception by the buyer.

CHANGES

Orders arising hereunder may be changed or amended only by written agreement signed by both the Buyer and the Seller, setting forth the particular changes to be made and the effect, if any, of such changes on the price and time of delivery. The Buyer may not cancel this order unless the Seller expressly agrees to such cancellation in writing. In such event, the Seller will advise the Buyer of the total charge for such cancellation and the Buyer agrees to pay such charges, including, but not limited to, storage and shipment costs, costs of producing non-standard materials, costs of purchasing non-returnable materials, cancellation costs imposed on the Seller by its suppliers and any other cost resulting from cancellation of this order by the Buyer which is permitted by the Seller. Certification of such costs by Seller's independent financial advisors shall be conclusive on the parties.

DELIVERY & DESPATCH DATES

In the case of products delivered within the United Kingdom, the Seller will, unless otherwise stated, arrange carriage and freight and insurance against loss or damage in transit. Risk in the products will pass to the Buyer at the time of delivery or if the Buyer or agent fails to take delivery of the products then at the time when the Seller has tendered delivery of the products. Should the Buyer require a special method of transport the cost will be to the Buyer's account. In all other cases, sales are made ex-works and delivery of products to the carrier at the Seller's plant or other loading point shall constitute delivery to the Buyer and regardless of shipping terms, all risk in the products shall pass to Buyer at that time. Where the risk in the products has not passed to the Buyer, the Seller shall accept responsibility for loss or damage in transit provided that it is given written notice of such damage within two days of the actual delivery date, and for non-delivery provided that it is given written notice of such non-delivery within four days of the contracted delivery date. The Seller reserves the right to make delivery in installments, all such installments to be separately invoiced and paid for when due per invoice, without regard to subsequent deliveries. Delay in delivery or any other breach affecting, any installment shall not relieve the Buyer of the Buyer's obligations to accept remaining deliveries. Immediately upon the Buyer's receipt of any products delivered, the Buyer shall inspect the individual items and shall notify the Seller in writing of any claims for shortages, defects or damages and shall hold the products pending the Seller's written instructions. If the Buyer shall fail to notify the Seller within two days after the Buyer has received the products, such products shall conclusively be deemed to conform to the terms and conditions and to have been irrevocably accepted by the Buyer. Although the Seller shall use all reasonable efforts to meet the contracted delivery date, such date is an estimate only. The Seller shall not be liable in any circumstances for loss, whether direct or consequential, arising from delay in delivery. Acceptance and completion of orders are subject to the Seller being in possession of all licenses, authorizations and approvals required for the purpose of the supply of the products by the Seller to the Buyer. In the event of the Seller at any time failing to be in possession of such, licenses, authorizations and approvals it shall be entitled to cancel the contract by written notice to the Buyer without any liability on the part of the Seller. The Seller shall not be liable for any loss, damage or penalty as a result of any delay in or failure to manufacture, deliver to any cause beyond the Seller's reasonable control, including unsuccessful reactions, embargo or other governmental act, regulation or request affecting the conduct of the Seller's business, fire, explosion, accident, theft, vandalism, riot, acts of war, strikes or other labor difficulties.

PAYMENT

Terms of sale are pre-sent payment and/or alternatively after credit account opened within our system a net 30 days of date of invoice, unless otherwise stated. If the Seller is concerned as to the financial ability of the Buyer to pay in full at the due date, the purchase price of the products, the Seller may, without notice to the Buyer, delay or postpone the delivery of the products; and the Seller is authorized to change the terms of payment to payment in full or in part in advance of delivery of the entire undelivered balance of said products. In the event of default by Buyer in the payment of the purchase price or otherwise, of this or any other order, the Seller may defer delivery, cancel this contract, or sell any undelivered products on hand for the account of the Buyer and apply such proceeds as a credit without set-off or deduction of any kind, against the contract purchase price, and the Buyer agrees to pay the balance then due to Seller on demand. The Buyer agrees to pay all costs, including, but not limited to reasonable legal and financial fees and other expenses of collection resulting from any default by the Buyer in any of the terms hereof.

TAXES AND OTHER CHARGES

Any value added tax, sales tax, excise tax, duty, customs, inspection or testing fee or charge of any nature whatsoever imposed by any governmental authority, on or measured by the transaction between the Seller and the Buyer shall be paid by Buyer in addition to the prices quoted or invoiced. In the event the Seller is required to pay any such tax, fee, or charge, the Buyer shall reimburse the Seller; or, in lieu of such payment, the Buyer shall provide the Seller, at the time the order is submitted, an exemption certificate or other document acceptable to the authority imposing the tax, fee or charge.

WARRANTIES AND LIABILITY

Seller warrants that its products shall conform to the description of such products as provided to the Buyer by the Seller in the Seller's product listing, analytical data or other literature. The Seller shall not be liable under this warranty in the event that the Seller determines, in its sole discretion, that the Buyer has misused the products in any manner, has failed to use the products in accordance with industrial standards and practices, or has failed to use the products in accordance with instructions, if any, furnished by the Seller. There are no representations, agreements, promises or understandings between the Buyer and the Seller that are not expressed herein and the Seller shall not be liable to the Buyer in respect of any such matters. The Seller's sole and exclusive liability and the Buyer's exclusive remedy with respect to products proved to the Seller's satisfaction to be defective or non-conforming shall be replacement of such products without charge or refund of the purchase price, in the Seller's sole discretion, upon the return of such products in accordance with the Seller's instructions. The Seller shall not in any event be liable for direct, indirect, incidental or special damages of any kind resulting from any use or failure of the products, even if the Seller has been advised of the possibility of such damage including, without limitation, liability for loss of use, loss of work in progress, downtime, loss of revenue or profits, failure to realize savings, loss of products of the Buyer or other use or any liability of the Buyer to a third party on account of such loss or for any labor or any other expense or for any damage or loss occasioned by such product including death, personal injury or property damage.

BUYER'S USE OF PRODUCTS

The Seller's products are intended primarily for laboratory and manufacturing purposes and, unless otherwise stated in the Seller's product listing furnished to the Buyer, are not to be used for any other purposes, including but not limited to, in vitro diagnostic purposes, in foods, drugs or medical devices. Buyer acknowledges that the Seller has not tested the products for safety and efficacy in food, drug or medical devices, unless otherwise stated in the Seller's literature furnished to the Buyer. The Buyer expressly represents and warrants to the Seller that the Buyer will properly test, use, manufacture and market any products purchased from the Seller and/or materials produced with products purchased from the Seller. The Buyer has the responsibility to verify the hazards and to conduct any further research necessary to learn the hazards involved in using products purchased from the Seller. The Buyer also has the duty to warn the Buyer's customers and any auxiliary personnel (such as freight handlers, etc.) of any risks involved in using or handling the products. The Buyer agrees to comply with instructions, if any, furnished by the Seller relating to the use of the products and not misuse the products in any manner. If the products purchased from the Seller are to be repackaged, relabeled or used as starting material or components of other products, The Buyer will verify the Seller's assay of the products. No products purchased from the Seller shall, unless otherwise stated, be considered to be foods, drugs, or medical devices.

DEFECTS, WARRANTY

The buyer is obliged to check goods immediately upon receipt. The buyer shall notify the Seller of any defects within 7 days after receipt of the goods. The buyer's notice of defect shall be in writing and fully substantiate the alleged defect. If the Buyer fails to notify the seller, it is expressly agreed that the goods delivered are fully accepted. The Buyer's claim under this warranty shall be limited to the replacement of the defective goods or the crediting of the product value. No products are to be returned without written approval by the Seller. The Seller is not liable for any misprints or mistakes in the product listings as to the best of our knowledge, all information stated is correct.

INVALIDITY

Should any provisions of these Terms and Conditions be totally or partly invalid, this will not affect the validity of the remaining terms. Any invalid provision shall be replaced by the valid provision, which comes closest to the commercial purpose.

GOVERNING LAW

All disputes as to the legality, interpretation of these terms and conditions, shall be governed by the laws of England for English Speaking countries and Spain for Spanish Speaking countries. For any other, ND Pharma reserves absolutely the right to decide jurisdiction.

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ND Pharma & Biotech

Making Life Better

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