

Contacts	
Website	toxicon.it
E-mail	info@toxicon.it
Head office	Via Robolini 1, 27100 Pavia, Italy
Tel	+39 0382 1938015
Contact	Raffaella Butera, MD
Directors	Raffaella Butera, MD
Ownership	Private company
Locations	Italy
Founded	2010

Overview

Toxicon provides a wide range of consultancy and regulatory services in the areas of toxicology, pharmacology, occupational medicine, products regulatory compliance and consumer safety for companies, institutions and for the general public.

Toxicon offers clients its know-how based on solid academic training in risk assessment and a deep understanding of clients' needs. Toxicon provides consulting services to both large companies and SMEs; approximately 40% of these activities are performed for international customers. Moreover, Toxicon works in partnership with institutions, industries and associations on R&D and compliance projects.

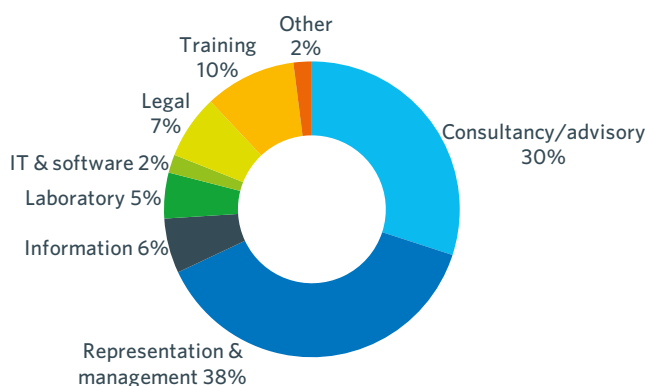
The team of specialists consists of toxicologists, pharmacologists, physicians, biologists, chemists, economists and lawyers: the core belief in Toxicon is that complex problems can be successfully and qualitatively solved through teamwork.

Vital statistics

2022/23

No of offices	3
No of countries represented	1
Staff: group	9
Staff: chemical service provision	7

Service area breakdown



Services provided

We have always been active in the area of toxicology and risk assessment; therefore, we have the expertise to enable enterprises to handle chemicals properly and safely. We want to make our in-depth professional knowledge available to companies and stakeholders. We have personally experienced the evolution that led to the current regulations, we know the keys to interpreting them correctly and applying them appropriately.

We bring to companies our unique expertise that no other consultancy firm can offer: before we were at Toxicon, we managed tens of thousands of cases of poisoning and accidental ingestions, adverse drug effects, occupational diseases due to workplace exposure, spills, chemical accidents and maxi-emergencies.

Therefore, when the ultimate aim of regulations is the protection of human health and the environment, we know what we are talking about. We know this concretely and we put this concreteness into all the activities and assessments we carry out for companies.

Overall services

- Support for companies and guidance on regulatory interpretation
- Strategies and project management for regulatory compliance
- Auditing
- Support for dialogue with the authorities

Toxicological risk assessment

- Expert advice and consultancy
- Human and environmental toxicological risk assessment reports for chemicals, products, consumer exposure, workplace exposure and plant emissions

REACH

- Consortia management and data sharing agreements
- Data gap analysis and testing strategy for substances and groups of substances
- REACH registration dossiers (all types of dossiers, eg lead or member registrant, substances, intermediate, PPORD)
- Chemical Safety Assessment and Chemical Safety Report (CSR)
- Full support during substance and dossier ECHA evaluation
- REACH authorisations dossiers including SEA
- REACH restrictions compliance
- SCIP database notifications

Safety Data Sheets (SDS) and Exposure Scenarios (ES)

- Management of SDS flow in the company organisation, development of checklists and procedures
- Elaboration of SDS and e-SDS, ES for mixtures
- Compliance check with ES, scaling, CSR-DU development
- Check of existing SDSs to improve document quality

CLP and GHS

- Hazard assessment of substances and mixtures, classification and labelling
- Notification to ECHA C&L Inventory and to PCNP for emergency health response on mixtures
- Labelling of products

Biocidal products

- Transitional measures to BPR (ie assessment and management of national requirements)
- Preliminary assessment of formulae to check substances of concern and ED assessment of coformulants
- Product preliminary risk assessment report, including risk assessment for human health, animals and environment
- Data sharing agreements for authorisation
- Support for dossiers of active substances
- Biocidal products authorisation at national and EU level, including support in testing (phys-chem, efficacy, methods), risk assessment report, IUCLID dossier and Summary of Product Characteristics
- Support for dialogue with the authorities during dossier evaluation

Cosmetics

- Preliminary assessment of formulae
- Advice on testing
- Safety assessment, product information file (PIF), labelling
- CPNP notification

Food contact materials

- Advice for materials and products testing
- Assessment of risks due to with constituents transferred to food
- Declarations of compliance

RoHS

- Compliance assessment along the supply chain
- Advice for materials and products testing

Toy safety

- Compliance with essential and particular safety requirements with special reference to chemical properties
- Advice for product testing and risk assessment of relevant chemical constituents

Medicines

- Common Technical Document (CTD) for non-clinical and clinical modules
- Genotoxic impurities assessment
- PDE assessment
- Provisional OELs and OEBs for APIs and other chemicals
- Environmental risk assessment

Medical devices

- Chemical and biological characterisation, biological evaluation
- Extractables and leachables assessment

Occupational medicine

- Risk assessment and management (CAD, CMRD)
- Provisional OELs for unregulated chemicals

Legal advice

- Intellectual property
- Data sharing
- Protection of confidential business information
- Contract management and contract editing
- Support for dialogue with clients and suppliers
- Counselling and support to companies in case of enforcement

Education

- Training and education for companies, universities and institutions

Corporate developments and achievements

2010	Established as a private limited company, both senior and junior professionals converge in Toxicon to provide companies with toxicological risk assessments and services for REACH and CLP
2011	In partnership with a prestigious law firm, Toxicon sets up the Legal Business Unit
2013	Toxicon services extend to cosmetics and food contact materials
2015	The Biocides Business Unit is fully operational
2018	Toxicon activities in product safety, medical devices, healthcare and pharma areas are further enhanced
2020	During the most acute phase of the COVID-19 pandemic Toxicon – in addition to its regular activities – serves the numerous requests coming from manufacturers and users of disinfectants. Toxicon schedules daily educational webinars on toxicological and regulatory issues that become a regular meeting time for clients and partners to stay in touch even during the lockdown period

Case study 1

United we stand: when the creation of a Consortium strengthens companies compliance with chemicals regulations

Toxicon catalysed the aggregation of more than 40 manufacturers and importers of similar substances, channeling the commitment of players in a complex supply chain unfamiliar with the REACH Regulation. The identification of solid scientific criteria to support the appropriateness of including these substances in a single category has allowed a testing and evaluation strategy (shared with ECHA) with an economic advantage for all consortium members at equal data value.

The close cooperation between the companies in the climate of technical trust that was created made it possible to successfully address and resolve each potential issue with the full knowledge of the companies. Particularly noteworthy is the involvement in the activity of many SMEs whose awareness of the importance of the European chemicals strategy for safe management is growing day by day.

Case study 2

Successful legal litigation with the support of Toxicon expertise

The presence of an undesirable substance in a raw material used for a medical device could have created a severe problem for the manufacturing company. Toxicon performed a targeted and thoughtful assessment, identifying the allowable exposure level according to scientific literature and substance behavior in animals and humans, and by comparing such level with the amount detected in the medical device.

This made it possible to resolve the issue, reconciling the requirements of the regulations, the safety for the end consumer, the benefits to his health and, last but not least, the company's business on this product. We were glad to support the company in this situation, because we had the opportunity to give appropriate consideration to the needs of all stakeholders in the full respect of business, regulations, science and health.

Staff selection

Raffaella Butera

Founder and Director of Toxicon, physician, she offers to clients more than 30 years' experience in medical toxicology and regulatory affairs. "In Toxicon we provide companies with a unique point of view in the application of chemicals regulations: that of someone who – concretely – knows what it means to protect human health."

Arianna Brunoro

Senior Consultant, biologist, she offers to client highly qualified toxicological and regulatory consultancy. "Compliance with regulations is a crucial aspect in ensuring and improving the high quality of the environment and the human life, a fundamental key to a healthy future generation."

Fabio Lunghi

Senior Consultant, chemist, he offers to clients an in-depth regulatory knowledge and a rigorous approach to risk assessment. "In our work at Toxicon, the objective of evaluating a product is to identify and describe the conditions under which the risk can be controlled."

Massimo Zen

Senior Consultant, chemist, he offers to clients an extensive laboratory experience and expertise in risk assessment. "In our evaluations, the interpretation of the significance of the laboratory data gives depth and value to the analytical effort."

Daniele Campi Martucci

Senior Consultant, economist, he offers to clients a high sensitivity to small enterprises needs. "The attention to small and medium-sized enterprises is crucial: at Toxicon we have developed SME-friendly services and activities to ensure proper chemical management even in the smallest enterprises."

Federica Butera

Senior Consultant, architect, she offers to clients a key reference point for the management of their regulatory projects with Toxicon. "The world of enterprise is all around us: we exchange needs, we experience, we build relationships, thanks to and with enterprises. Business is about bringing people to people."

Salvo Dell'Arte

Senior Partner of Law Firm Dell'Arte, lawyer and professor at the University of Turin, he offers to clients its profound expertise on commercial, industrial and copyright law. "The European Data Sharing Regulation has provided clarity, establishing in law the principles and rules that we ourselves had advocated since the early days of REACH."



Global Service Providers Guide 2024.

Fourteenth edition

The guide to global chemicals
management and control services

Sponsored by

knoell



worldwide
registration