



ABOUT ARCUS COMPLIANCE

With nearly 25 years' collective experience from across the vapour industry, Arcus Compliance are the regulatory compliance partners of choice. Our proprietary tools and professional services take all of the headache and worry out of the complex and ever-changing regulatory landscape.

We have successfully built and implemented global compliance strategies for the biggest brands in the business. We are highly experienced in working within regulated regions such as Europe, North America and UAE, as well as non-regulated countries that follow the Globally Harmonised System (GHS) of Classification and Labelling of Chemicals. We're also actively working with brands that operate in countries that will be regulated in the future.

We are Board Members of the UK Vaping Industry Association (UKVIA) and advise its Standards Committee, aimed at promoting more positive attitudes towards vaping, and representing the wider industry's interests in safety, compliance and product standards.

Arcus Compliance's core business values of transparency, reliability, consistency and efficiency are intended to achieve a trusted partnership with our clients. Throughout the vaping industry, we are renowned for being:

- Straight talking - we get straight to the point and tell you exactly what you need to do
- Commercially minded - we keep in mind the needs of your business
- Easy to work with - we build our service around your company and ensure it helps, not hinders
- Passionate about client success - we want to help you win!



'We pride ourselves on applying our extensive knowledge in a variety of ways to help you achieve your goals with maximum efficiency.'

- Lee Bryan, Director & Founder of Arcus Compliance

Compliance - with a difference

Arcus Compliance was formed in 2017, with a vision to help smaller brands tackle the more complex issues around compliance in a newly-regulated market, thereby offering an alternative to the big tobacco firms. With a particular focus on the detail that comprises effective compliance, including multi-lingual systems and documentation, through to the product stewardship, our core compliance methodology and professional approach has enabled clients to focus on growing their businesses, in both foreign and domestic markets.

Since then, Arcus Compliance has rapidly built a broad and diverse portfolio of clients and shared their vast experience and knowledge across the industry. Our role is to educate not just our clients, but also the decision-makers, on the practicalities of regulation, the importance of compliance and ultimately preventing businesses from falling foul of the law.

We were established to meet complex client needs, with a whole range of services available.

These include fully retained consultancy, proprietary Software as a Service (SaaS) tools, as well as bespoke support. Our professional products and services are designed to help you build an effective compliance strategy. Here are just a few of the ways Arcus Compliance will enable your company to embark upon the compliance journey with confidence:

- Quality Management consulting
- Compliance strategy consulting
- Lab testing project management
- Technical dossier authoring
- Classification, Labelling & Packaging (CLP) review
- Tobacco Product Directive (TPD) submissions & review
- XML authoring, analysis & debugging
- Banned substance screening
- Safety Data Sheet Authoring (MSDS)
- Safety Concerns Tracing (Recital 45 of TPD / Article 5 of GPSD)
- A fully outsourced regulatory compliance department

LEGAL & REGULATIONS

De-mystifying compliance in the changing landscape

The global regulatory landscape is an ever-changing labyrinth of directives, obligations and regulations.

Is your business and its products fully compliant in the markets it serves? Do you regularly screen and monitor all your products and their ingredients? How will you keep up to date with all the latest changes and requirements?

Regulators are putting more focus on notifications, and enforcement action is increasing. A robust compliance strategy will not only keep your products for sale on the market, but will also prevent huge fines and stiff legal sanctions. For your brand to adapt and survive in this changing climate, it is essential to ensure regulatory compliance is high on your agenda - as much as marketing or sales.

TPD Directive 2014/40/EU

The Tobacco Products Directive (TPD) is a major piece of EU legislation that impacts every aspect of vapour manufacture and distribution, imposing increased regulation on the vapour industry. It is by no means the only rules and regulations your business must navigate. In fact, one of the frequent issues our clients face is actually being able to accurately interpret which regulations apply to their products.

CLP Regulation (EC) No 1272/2008

The Classification, Labelling and Packaging regulations (CLP) require your business to communicate to consumers at the point of transaction - which includes in an online environment. Any hazard warning statements or pictograms which appear on the product's packaging must also be displayed on your e-commerce platform. European enforcement bodies regularly investigate this, so it's imperative your brand establishes its classification across all channels.

GDPR (EU) 2016/679 GDPR

Have you considered the impact of the General Data Protection Regulation (GDPR) on how you run your business? Do you manage a fully compliant system for consumer or safety data? Health data requires a higher level of compliance and if GDPR restrictions are breached - even inadvertently - your company could be liable for unlimited fines under EU law.

Arcus Compliance - the regulatory compliance partner of choice

With specialist knowledge of every regulation that impacts your vapour business, Arcus Compliance are the ideal compliance partners. We are continually scanning the horizon for potential risks and ensure resilience in readiness for challenges. We are trusted touchpoints for the Medicines and Healthcare Products Regulatory Agency (MHRA) and are in regular dialogue regarding areas of concern and any substances that may be under scrutiny.

Compliance is much more than having a product notified for TPD. Following a structured product stewardship methodology and quality management processes will help to identify and mitigate risks. The relationships we have built with industry bodies and regulators ensures that a steady stream of the most up to date advice is available to our clients. Ease the regulatory pressure and ensure full peace of mind with Arcus Compliance.

Compliance is an ever moving target - meaning an agile, knowledgeable partner is vital in ensuring your business is always ahead of the regulatory curve. Arcus Compliance offer the technical expertise, industry-insider information and professional advice your business needs to stay legitimate and profitable.



PARTNERSHIPS & MEMBERSHIPS

Arcus Compliance work with high quality partners to deliver a comprehensive service for all clients. Some of our key partners include:



In 2019 we established our Primary Authority Partnership with Peterborough and Cambridge Trading Standards body. This Primary Authority Partnership was formed to obtain assured advice directly from Trading Standards, which is then relayed to our clients for implementation. The trusted working relationship we have created provides full peace of mind to our clients on specific issues, as well as enabling regular contact to relay industry challenges and collaborative working with Trading Standards towards effective resolutions.



As key partners with World Vape Dubai, the world's largest vaping event, we regularly exhibit to share our knowledge and showcase our expert compliance solutions. During the events, our immediate compliance health checks and signature compliance clinics have proved incredibly popular. We also offer a bespoke 60-minute telephone compliance consultation for all exhibitors, and host engaging and energising panel meetings and speaker sessions.



1 account offer a free age verification solution which is a highly effective compliance tool. It prevents under-age sales while ensuring a smooth and seamless transaction throughout the online checkout process.



The partnership with Vape Jam, organisers of the UK's leading vapour industry events, offers existing and prospective clients the opportunity to meet with like-minded professionals at vibrant events, to network and learn about compliance within the vapour industry.



As Board Members and Standards Committee representatives, Arcus Compliance have a seat at the leading forum for supporting, developing and promoting the £1bn vaping industry in the UK. We contribute directly to the conversations that impact our clients regarding compliance, offering practical guidance and advice at the highest level.



We are speaker partners on compliance at Europe's largest B2B and consumer show, VaperExpo. Our role is to attend and exhibit at the events, imparting our professional expertise through inspiring keynote speeches and providing important regulatory compliance information to delegates.

CORE COMPLIANCE METHODOLOGY



In a regulated market such as the vapour industry, it is imperative that you have a system of controls to ensure and maintain internal standards.

To support this approach, Arcus Compliance have designed a CORE COMPLIANCE methodology to CONTROL, OBSERVE, REACT AND ESTABLISH your compliance strategy. CORE COMPLIANCE focuses on building the essential regulatory framework to ensure your products stay safely on the market.

By following these clear and comprehensive methodologies, vaping manufacturers, importers and distributors can develop genuinely robust processes and demonstrable due diligence, as well as meeting all regulatory obligations.

Our trademarked CORE COMPLIANCE methodologies advise on all facets of the following:



Product Data

The fundamentals of the health aspects of product stewardship



Risk Management

Identifying and reviewing new and existing risks within your product stewardship and compliance. By going through this process, you will quickly identify risks and mitigate them with robust systems



Analytical Data

Testing, consistent dosing, methodologies and toxicology



Labelling & Packaging

External packaging, unit labels, local languages, warning symbols, child-resistant and tamper-evident certifications and safety data sheets



Quality Management

The systems that you have in place to ensure consistency of manufacture and quality



Consumer Safety

Post-sale exposure and ensuring your ability to monitor and process consumer data



Our tried and tested methodologies clearly illustrate how compliance requirements are taken care of at every stage of the product lifecycle.

CORE COMPLIANCE METHODOLOGY

CONSUMER SAFETY METHODOLOGY

The Consumer Safety CORE COMPLIANCE methodology focuses on your post-sale exposure and relates to your ability to monitor and process consumer data. If you employ these steps you will begin to build clearly defined processes and robust compliance, as well as meeting your regulatory obligations.



Adverse effects tracking

Tracking safety concerns (or adverse effects) around your products is a standard element of product stewardship and is now a legal requirement for the vapour industry. Safety concerns tracking is a requirement for most, if not all, of the regulated markets including Europe, Canada and the USA.



Local language

As with your labelling, packaging and documentation, you must be able to record everything in the local language. It is also wise to use a system that covers all time zones, to improve the volume of reports that come to you directly, instead of the member state regulator.



Consumer preferences

Member state regulators are keen to collect as much data as possible to assist in making crucial decisions around the further regulation of vapour products. It is not currently obligatory to undertake any consumer preference surveys, but if you do collect data on any of these subjects, then you are obliged to submit them annually.



Flavour preference

Flavour preference data is another heated debate amongst competent authorities, with many proposing a ban on all flavours other than tobacco flavours. If your brand is predominantly flavour based, then it is in your interest to collate data to support this.



Appropriately robust

You must have a suitably robust system to record and monitor the safety concerns and, where appropriate, to inform the competent authorities. You need to have a system that can cope with a batch failure and potential subsequent product recall. This system must work in all markets you operate in, as well as being appropriate for the volumes that you sell.



Severity rating

Having the ability to rate a safety concern is the difference between managing your safety concerns internally, rather than pushing everything through the competent authority. Having control and managing your safety concerns in house before they are lodged with the regulatory bodies allows you to rate severity in house and quickly handle, close or escalate the issue.



Youth uptake

The data surrounding youth uptake is a hot topic with all competent authorities and any information they can collate on this topic is of interest. It is advisable you do everything possible to avoid your brand being associated with any "youth uptake in vaping" news coverage.



PRODUCT & SERVICE INFO



Arcus Compliance have tailor-made the first and only vape focused safety concern tracking white-label software. It enables our clients to comprehensively and effectively handle safety concerns across 24 different languages, 24 hours a day, 7 days per week - all through a single system.

VAPEVIGIL®'s easy to use client dashboard allows you to quickly review and action safety concerns, using our severity rating system. You can contact the consumer directly through the portal, using our anonymised communications to maintain GDPR protocols on sensitive data and then close, escalate or submit the report to the competent authorities as required.

Contact Arcus Compliance to arrange a free demo and discover how VAPEVIGIL® will make light work of product safety management.



PRODUCT & SERVICE INFO



The vapour industry's most trusted safety data sheet authoring service.

Professional safety data sheets form the first impression that regulators have of your business. Instil trust and confidence that your business handles safety with the due care and consideration it demands.

VAPESDS® is the industry's most trusted SDS authoring service. It has been used to create over 3372 different safety data sheets, for over 280 brands.

The proprietary tool is directly linked to one of the largest databases of flavour house concentrates, a banned substance screening tool and a toxicology studies database. With impeccable credentials and Arcus Compliance's professional support, VAPESDS® is well placed to deliver everything you need for your entire product stewardship.

Contact us to discuss how VAPESDS® can help you, just like it has for hundreds of other brands



PRODUCT & SERVICE INFO



Track all essential data at every level, including individual product, stock keeping unit and UFI (Unique Formulas and Unique Design) through the intuitive VAPEVISTA® dashboard.

VAPEVISTA® provides you with a comprehensive dashboard to record all important data regarding your vapour products and displays them in a format that is easy to use and manage. The dashboard will allow you to take a product through the entire stewardship and compliance process, ordering testing and building the product's compliance file.

VAPEVISTA® is your essential tool for creating a single point of truth and robust due diligence.

Contact Arcus Compliance to arrange a free demo and find out how VAPEVISTA® streamlines the data management of your products across the globe.



OTHER PRODUCTS & SERVICES

Your Outsourced Compliance Department

Let us take the weight off your shoulders. Arcus Compliance offer a fully outsourced compliance department for medium to large brands, without the need for internal compliance resources - and for a fraction of the cost.

Arcus Compliance enables you to completely outsource your product stewardship and regulatory compliance with one expert supplier, while adding intrinsic value and specialist knowledge to your brand.

Our outsourcing packages range from retained advisory services, right through to a fully managed outsourced compliance department, offering a talented team of compliance professionals to cover your obligations for all regulatory landscapes. We also offer bespoke services for large overseas companies, who may require local compliance knowledge and multi-lingual support.

Get in touch to find out how we can transform your business' approach to compliance, and take care of every element of the process on your behalf.





General Regulatory Project Management

With a wealth of experience across manufacturing, distribution and regulatory affairs, the Arcus Compliance team can offer strategic leadership and unparalleled acumen. Over the years, we have delivered hundreds of projects to overhaul and streamline complex compliance processes, for many of the world's biggest brands. Rely on our team's knowledge and understanding to ensure that systems of work and compliance strategies are considered in detail and deployed effectively.

Analytical Services

Arcus Compliance's highly-skilled team include in-house data analysis experts, who will work closely with you. We will help you to gain insight, establish patterns, issues or trends, whether it's product or safety data, or reviewing customer research.

Translation Services

We also work with a translation house who provides us with language translations on official documents, packaging and other content when required. The translation house can translate into all 24 EU languages, as well as Russian, Arabic, Hindi and Mandarin. The service is quick and cheaper than most of our competitors.



CASE STUDIES & TESTIMONIALS

Arcus Compliance are proud to work with a broad portfolio of vapour clients from across the globe. Our aim is always to guide, support and partner with clients, to ensure compliance is taken care of, leaving you to focus on a sustainable and profitable business.

We have supported some of the world's biggest vaping brands to achieve and maintain their coveted compliant status. See what our clients had to say about their experience of working with Arcus Compliance:



'We, as a company, joined with Arcus Compliance as a retainer client to get our products TPD-approved. We are still in the process, but could not have asked for a better experience. Every single member on both sides is totally on point; communication is tight, tasks are being handled in a timely manner, and we can operate normally without too much intervention. We look forward to a continued relationship with Arcus!'

- Riley Legaspi, Compliance Director, BLVK Unicorn



'We began working with Arcus Compliance in 2017, after we identified some errors in our notifications. The guys at Arcus took on a project with a short deadline between Christmas and New Year and delivered with a couple of days to spare. It was so nice to find a supplier in this industry, who under promises and over delivers! We are now into our second year with them and beginning to roll out the CORE COMPLIANCE product stewardship methodology, to further improve our due diligence process.'

- Brett Zillman, Director of Operations, ARC Distro

CASE STUDIES & TESTIMONIALS



'Two years of partnership with Arcus Compliance has taken the stress, confusion and complications out of arduous regulatory compliance. The conveyance of compliance through all of its stages was highly convoluted. Arcus Compliance ensured that we now cover all areas of compliance appertaining to our business, even in areas we did not know we were lacking. In a market where our compliance strategy is developing and dynamic, we needed solid guidance to future-proof our business model. The Arcus Compliance team are easy to talk to and take the guess work out of compliance issues. In our opinion, their dedication and attention to detail makes them the only compliance company you can trust with your business and future.'

- Harry Owen, Managing Director, UK Aspire Vendor



'Arcus Compliance has been handling all of Cosmic Fog's European testing and compliance for 2 years. Lee Bryan, Managing Director of Arcus Compliance has handled our compliance matters for roughly 4 years. During that time, we have built an amazing working relationship, as well as a strong personal friendship. We have all heard horror stories regarding TPD compliance - I consider myself lucky to have found Lee early on, and so never had to experience any of those firsthand. Lee and his team always get the job done.'

- Bert J. Ruiz, Vice President of Business Development, Cosmic Fog



'We were working with Arcus Compliance for almost 2 years throughout our involvement with ASPIRE, as UK distributors. So when the time came for us to improve our internal regulatory affairs, the decision to appoint Arcus Compliance as our retained partner was an easy one. We are already undergoing an extensive improvement programme in core compliance, that will see our due diligence and documentary evidence increase significantly.'

- Ash Heaton, Director, ifancyone



JOIN US ON THE JOURNEY

In need of further guidance? Contact our friendly and professional team to discuss your requirements.

Whether it's a fully outsourced compliance department, or simply supporting your business to take its first steps on the path toward compliance, we can offer a free, no-obligation quote.

Why not start with a CORE compliance health check? Our detailed review process will benchmark your current status, and provide you with a roadmap to make the necessary changes to create a robust compliance strategy.

At every stage of the journey, you're in safe hands with Arcus Compliance - the vapour industry's preferred compliance partner.

Contact Arcus Compliance

By telephone: +44 (0)1547 520 483

By email: info@arcuscompliance.com

Online: www.arcuscompliance.com

By post: Arcus Compliance
5 West Street
Knighton
Powys
LD7 1EN
United Kingdom

#ASKARCUS





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