

The Outsourced Regulatory Department

INFORMATION BROCHURE



Introducing the modern outsourced regulatory department

Murzilli Consulting is a digital aviation consultancy firm founded in 2020 by Lorenzo Murzilli and based in Bern, Switzerland, with further subsidiaries in Spain, UK, Germany, Hungary, and Poland. Our organisation is committed to helping our clients succeed with their regulation and compliance strategies. We do this by acting as a Digital Outsourced Regulatory Department and working with clients to support them in establishing a high-performing internal regulatory function. Our primary focus is on emerging technologies in the sectors of advanced air mobility, drones, UTM and U-space (including all deriva-tive focuses).

Our team offers governments and private enterprises alike the opportunity to establish a high-performing regulatory function by leveraging our team's expertise as a digital outsourced regulatory department. Murzilli Consulting also can take a leading role in supporting organisations to gain project-based approvals. This includes realising strategic operational goals for projects that need design certifications, SORA approvals and CE markings, among other services. Our customer base is unrivaled in the consulting industry and reflects the trust that the vast majority of leading drone organisations have in our services.

Meet our expert team



Eszter Kovacs
Co-Founder and Managing
Partner



Lorenzo Murzilli
CEO and Managing
Partner



Graham TrickeySenior Consultant Technology and Regulations



Mehran Ahmady Senior Consultant -U-space and UTM



Juanjo SolaDirector - Regulatory Affairs and Commercial Space



Richard Boden

Director
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Associate

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Services



The outsourced regulatory affairs office



When it comes to regulation, we're dedicated to getting every step right. And, we have the people to get you there.

Our founder and CEO, Lorenzo Murzilli is a former regulator and aerospace engineer by training. He was also the leader of the Joint Authorities for Rulemaking on Unmanned Systems WG-6 from 2015 until December 2022 where he oversaw the work of more than 100 professionals in several task forces developing recommendations for the safety and risk management of drone operations worldwide.

From his decades of aviation experience, Lorenzo Murzilli founded Murzilli Consulting to create an outsourced regulatory affairs office to help drone organisations understand and implement new and existing aviation regulations.

The team he put together consists of aviation professionals specialised in all areas of the traditional and advanced aviation industry, which means that the Murzilli consultants can support your board, C-level executives and engineering teams with strategy, regulations and policy.

Regulatory strategy

- •Regulatory strategy and execution for international product deployment
- ·Regulatory gap analysis
- •Regulatory pathway optimisation and acceleration strategy
- •Regulatory guidance during funding rounds, regulatory roadmaps and persuasive investor pitches
- •Function as an advisory board member to provide guidance on regulatory strategy and execution

Organisational development strategy for design, production and operations

- Organisational requirements
- ·Organisational structure
- ·Roles and responsibilities
- Processes and procedures
- ·Recruiting support for key personnel



Aviation authority liaison

- Single point of contact for aviation authorities
- Preparation support
- a. Briefing documents
- b. Rehearsals
- Organisation and management of critical meetings
- a. Briefing and debriefing
- Insider information gathering

Safety oversight meetings

Meeting strategy and inspection readiness

Stakeholder management

- •Regulatory stakeholder management
- ·Stakeholder mapping and advice
- •"Best player" recommendations, such as U-space service providers (USSPs)

Merger and acquisitions (M&A)

•Support performing strategic due diligence on target firms for merger and acquisition programmes

International and standard development organisations (SDO)

- •Report on SDO activities worldwide, such as EUROCAE, RTCA, ASTM, etc.
- •Report on activities of international organisations, such as ICAO, JARUS, etc.
- •Report on regulatory working groups, such as EASA, FAA, etc.

We will provide all services listed under the project goals at the customer's request and unlimited back-end support from our entire team. We are constantly in contact with regulators worldwide; we attend all relevant meetings and conferences; and, we are part of all important standardisation efforts. Our network is unmatched, and our reputation is unrivalled. We know what each authority is looking for and how to get there. The knowledge, network and expertise of Murzilli Consulting will be available to you through our outsourced regulatory affairs office.

The different subscription tiers represent the amount of front-end time and flexibility that is available. This includes things like meetings, weekly calls and appointments, among others. The lowest tier allows only for a fixed schedule, whereas the highest tier offers full flexibility, including real-time support.

Tier 1

Our package for small organisations attempting to tackle regulatory challenges for the first time.

- Access to entire team
- Two one-hour calls (on a fixed date and time) per month with our team
- Monthly regulatory meeting

Tier 2

Our most popular package for organisations looking to build a better regulatory and compliance foundation for a more resilient organisation.

- Access to the entire team
- Direct access to our team's calendar for better planning
- → Four one-hour calls per month with our team
- Monthly regulatory meeting, including a written report on regulatory information and updates

Tier 3

Our most comprehensive package for organisations who would like support for any and all of their regulatory needs that Murzilli Consulting has expertise in.

- Access to the entire team.
- Direct access to our team's calendar for better planning
- ✓ Eight one-hour calls per month with our team
- Monthly regulatory meeting, including a written report on regulatory information and updates
- Access to a chat platform like Slack or Signal for on-demand consulting needs.

Up to 50% of the fee payable in equity

Services



Project-based services



Initial project assessment

Our initial assessment will evaluate how ready your project is to tackle the required regulatory hurdles. We'll perform this assessment on-site at the customer's primary location, where we'll do an in-depth review of your organisation and product maturity (please note that our review can last up to 3 days). After our assessment is completed, we'll provide you with a report of our findings in the form of a health check and recommendations.

Operational authorisations (SORA) 1

Murzilli Consulting is able to support organisations in gaining operational authorisations (SORA) for any SAIL² in any country where SORA is accepted. Our team has extensive expertise that also allows us to safely navigate the challenges of SAIL III and IV.

Our operational authorisation services include the following:

- 1. Initial project assessment
- 2. End-to-end project management in our project management software
- 3. Review and guidance on the client's concept of operations (ConOps)
- 4. Review and guidance on any existing client documentation to support regulatory authorisation applications

- 5. Review of the client's compliance strategy based on each SORA requirement
- 6. Review and guidance on the client's SORA documentation
- 7. Review of the client's containment strategy (basic vs advanced)
- 8. Support with the creation of compliance documentation (including templates)
- 9. Review of the client's deconfliction scheme for air risk (when applicable)
- 10. Validation of the client's operational procedures and emergency response plan (ERP) training
- 11. Support responding to feedback from authorities until the project is completed.

Specific Operations Risk Assessment

² Specific Assurance and Integrity Levels

The following additional services can be selected as add-ons during the initial project assessment (if requested specifically by the client):

- Gathering information for preparing the application
- Document writing services for the following:

Concept of operations (ConOps)

Specific Operations Risk Assessment (SORA)

Operations manuals

Training logs for personnel

Maintenance manuals

Inspection reports

Functional hazard assessment (FHA) appraisals

Design and installation appraisal (D&IA)

Emergency response plan (ERP)

- · Any documentation required by an authority for project approval
- Enhanced containment design verification
- · Project set-up in the client's project management software of choice
- Definition of compliance strategy for each of the SORA requirements
- Development of the deconfliction scheme for air risk
- Development of a strategy for containment (basic vs enhanced)
- Third-party validation management, such as EASA or performed by Murzilli Consulting
- · Authority liaison and management





Murzilli Consulting can support clients in their endevour to achieve a Light UAS Operator Certification (LUC) in Europe.

Our services include the following:

- 1. End-to-end project management of the LUC application in one of our project management softwares
- 2. Review and update of any existing client documentation required for the certification
- 3. Compliance checklist management
- 4. Support responding to feedback from authorities until the project is completed

In addition to the baseline services mentioned above, the following add-ons are also available upon the client's request:

- Gathering information for the preparation of the application
- Writing and preparation of LUC manual documentation
- Project set-up in the client's project management software of choice
- Fully authority liaison and management



Design verification report (DVR) and type certification (TC)

Murzilli Consulting can help your organisation achieve the design verification report (DVR) from EASA for SAIL I, II, III and IV or to go through the type certification process from EASA, FAA or other authorities.

This service is broken down into two project phases.

Phase one: design verification report (DVR) / type certification (TC) application preparation

Design review (DR)

Before our clients apply for a design verification report (DVR) or a type certificate (TC), we require that they first complete a design review (DR). The DR ensures that the activity planned for the aircraft design is appropriate for the intended business, safety and design verification or certification objectives.

A completed design review (DR) before applying for the DVR or TC confirms that the aircraft design meets

the standards required by the authority (e.g. EASA or FAA), which establishes confidence for the final application.

Services:

- 1. End-to-end project management of the design review (including all necessary licenses)
- 2. Review and update of the client's airworthiness concept of operations (ConOps) and aircraft requirements document.
- 3. End-to-end support and guidance on documentation
- 4. Support meeting the requirements listed in the design review compliance checklist

In addition to the baseline services mentioned, the following add-ons are also available upon the client's request:

- Documentation writing and review for airworthiness ConOps
- Event management for the design review
- · Master of ceremony for the design review
- Report including the results and recommendations for the design review

Phase one: design verification report or type certification application preparation



In addition to the design review, we also require that clients establish a design management system (DMS) before they apply to the design verification report (DVR) or type certification (TC).

The design management system ensures that our clients have effective and transparent organisational processes and procedures (including flight testing). These are typically documented in a design organisation handbook (DOH).

The amount of effort and detail put into an organisation's DOH can vary significantly with the project's scope as well as the size of the organisation.



Services:

- 1. Support achieving the perfect balance between agility and stringent processes
- 2. Achieving the minimum requirements for an effective design management system (DMS)
- 3. Custom DOH templates
- 4. Review and update of the client's DOH

The following add-ons are also available upon the client's request:

- Gathering information for the DOH preparation
- · Creation and writing of DOH
- DOH training for all relevant employees of our client

Phase two: the design verification report or type certification

After completing phase one, we'll begin to support you with the design verification/type certification process.

Services:

- 1. End-to-end project management of the design verification report (DVR) or type certification (TC) project and coordination with the relevant aviation authority
- 2. Establishment of applicable airworthiness codes and certification/design verification basis
- 3. Support defining the design verification or type certification plan
- 4. Development and execution of a functional test-based programme, like the FAA's durability and reliability (D&R) process for small unmanned aircraft systems (sUAS) or flight test programme
- 5. Establish the compliance matrix to identify the applicable means of compliance (MoC) along with the evidence of compliance
- 6. Expert advice for compliance demonstrations
- 7. Assistance or direct project management of compliance demonstrations (testing, preparation of reports, analyses, simulations, etc.)
- 8. Creation of any compliance documentation or certification reports
- 9. Preparation and support with all authority meetings and correspondence with the relevant authority until the project's completion



The following add-ons are also available upon the client's request:

- · Design process defintion and implementation
- Design review process definition, including the definition of all design reviews (e.g. critical design review or final design review)
- End-to-end coordination and establishment of the design verification and flight test operations
- Development and execution of a functional test-based programme (SAIL II and III)
- Development and implementation of a demonstration test plan following ASTM standard F3478-204 (SAIL II and III)
- Preparation of flight test plans and flight test reports
- Preparation and review of technical publications
- Support with aircraft and system safety assessments (according to SAE ARP 4761 and SAE ARP 4754) in collaboration with our exclusive partner

- Assistance with or direct support with selected compliance demonstrations
- · Authority liaison and management
- Support with designated engineering representitive (DER) oversight and approval in collaboration with our exclusive partner

Under certain circumstances for SAIL II and III, approval can be obtained through a self-declaration of compliance to the national aviation authority (NAA). If this happens to also be the case for you, we'll help ensure that the process of legally self-declaring compliance for all operations is done correctly.

Aircraft and system safety assessment and development assurance

(including software and airborne electronic hardware)

Murzilli Consulting can provide your organisation with a complete set of safety and development assurance services in collaboration with our network of partners.

The following are available services:

- 1. Establishment of a safety programme plan
- 2. Development of aircraft and system functional hazard assessments
- 3. Development of reliability predictions
- 4. Development of failure mode and effects analysis (FMEA) or failure mode, effects and criticality analysis (FMECA)
- 5. Development of fault tree analysis
- 6. Development of particular risk analysis / common cause analysis
- 7. Development of system and aircraft safety assessments
- 8. Software and airborne electronic hardware validation covering the complete DO-178C and DO-254 lifecycle.





Assurance, safety and quality systems

Murzilli Consulting can support organisations to establish solid assurance, safety and quality management systems.

Services:

- 1. Third-party safety audit/evaluation of the client's organisation
- 2. Design organisation and related handbook
- 3. Production organisation and related handbook
- 4. Operations manuals
- 5. Safety management systems and related manuals
- 6. Quality management systems and related manuals

All of the services above also include:

- •Consultation with the the organisation's management to define how new process are to be integrated into existing workflows
- •Collaboration with the organisation's team to define the best processes and operations
- •Training for the organisation's team on any newly established system

Accident investigation and disaster preparedness

We support our clients in the most challenging of timest. Our trained accident investigators act as your organisation's Air Safety Investigators (ASI) both during official state investigations (e.g. in case of a formal NTSB, BEA, SUST, etc., investigation) as well as internal organisation investigations. Our accident investigation offer is structured in three distinct levels.



Level one: Prepare



Murzilli Consulting will help support organisations deal with the aftermath of an accident or disaster.

Services:

- 1. Establish an emergency response plan (ERP) proportional to the nature and size of the organisation
- 2. Establish an accident investigation process in collaboration with the organisation's top management to ensure a clear chain of command to make sure responsibilities are taken care of during a crisis
- 3. Clear communication guidelines and templates to help guide organisations through accidents
- 4. Training for your organisation's team on the acceptable behaviour to respond to an accident



Level two: Investigate

Murzilli Consulting will provide an independent accident investigation along with expert support during the investigation process.

Services:

- 1. Understand the events that led to the accident or occurrence
- 2. Identify the hazards and conduct a risk assessment
- 3. Provide recommendations to reduce or eliminate unacceptable risks
- 4. Communicate safety updates, findings and guidelines to appropriate stakeholders

The following add-ons are also available:

- •Establishment of an investigation team with the required skills and expertise to understand the findings of the risk assessment
- •Gather factual information pertinent to understanding the circumstances and events that occurred to lead to an accident
- •Reconstruct the accident to establish an exact sequence of events and relevant safety and contributory factors
- •Analyse available information to assess the risks and explain both the technical and operational underlying factors (including organisational) that caused the accident
- •Report on the concluded reconstructed events that led to the accident based on the collected and analysed information
- •Identify safety recommendations and actions to eliminate or mitigate the safety deficiencies identified by the investigation
- · Communicate these findings to relevant stakeholders



Respond

Murzilli Consulting only offers certain clients an on-demand (any time or day of the year) accident response service. This is an exclusive service provided on a subscription-only basis and guarantees that a Murzilli Air Safety Investigator (ASI) Consultant is dispatched worldwide in case of an accident within 24 hours of receiving the alert.

A Murzilli ASI Consultant will be deployed to support you during an official state investigation or as a member of any type of investigative team your organisation has created in response to an accident.

U-Space regulatory consulting and strategy

Murzilli Consulting can provide consulting services to authorities, government officials, cities and industry stakeholders to establish a U-space airspace.



Services:

- •Strategy and roadmap for the implementation of a U-space airspace
- •Stakeholder management for the implementation of a U-space airspace
- Support navigating regulatory pathways and strategic goals
- •Guidance on U-space regulations, including guidance on the acceptable means of compliance and the guidance materials (AMC/GM)
- •Support defining a specific U-space airspace, including the required and voluntary U-space services
- •Support with the establishment of the architecture, design and operational conditions of the U-space
- •Support with the establishment of U-space risk assessment guidelines

U-space service provider (USSP) certification

Murzilli Consulting can provide support to organisations looking to gain traction as leading players in the new U-space airspaces and are required to undergo the approval process as a U-space service provider (USSP).



Services:

- Support navigating regulatory pathways and strategic goals
- •Guidance on U-space regulations, including guidance on the acceptable means of compliance and the guidance materials (AMC/GM)
- •Guidance and support for the U-space service provider (USSP) certification process
- •Guidance and support for any and all USSP certification requirements, including legal or financial elements, organisational and managerial elements, as well as operational USSP deployment
- •Liaison management with the relevant aviation authority
- •Review of compliance documentation
- •End-to-end project management of USSP certification processes

UAS C-Class and CE marking

Murzilli Consulting provides services to help organisations comply with EU Reg. 2019/945, which is for the required certification from a notified body. Our team is able to accelerate the certification process and ensure that the time and effort for coordination and background checks with the notified bodies are reduced.

Services:

- Assessment of UAS C-Class and regulatory requirements
- Selection of a relevant notified body
- •Communication, background checks and process management with the notified body
- •End-to-end project management of the C-Class marking and CE marking
- •Review and evaluation of the design solutions, including functionalities, that are relevant for EU Reg. 2019/945 and prEN 4709 compliance
- •Review and evaluation of the required documentation, including design maintenance and customer documentation
- •Preparation and realisation of a gap analysis to check the design and documentation coverage for the required regulations and standards
- Test preparation review

The following add-ons are also available upon the client's request:

- •Preparation of a certification programme
- •Regulatory training on EU Reg. 2019/945 and the open category
- Supporting both evaluation and pre-certification tests
- •Preparation of any and all documentation required for certification

Third-Party validation for SORA Mitigations and Operational Safety Objectives (OSOs) at High Robustness

Murzilli Consulting is recognized as a competent third party by several national aviation authorities. We can therefore provide third-party validation activities for SORA mitigations and OSOs at high levels of robustness.

Services:

- •Function as a competent third party to validate mitigations and OSOs at high levels of robustness.
- •Manage the acceptance of the SORA application package from the relevant aviation authority as a third-party validator
- •Facilitate end-to-end project management for SORA validation and review
- •Review of the client's concept of operations (ConOps), application documentation, compliance strategy and SORA
- •Review of the client's containment strategy and deconfliction scheme for air risk
- Perform audit and desk reviews of the UAS operator, manufacturing and maintenance procedures
- ·Validate operational procedures and ERP training
- •Flight test programme review and acceptance (witnessing of flight tests)
- •Evaluate technical issuances with a declaration from Murzilli Consulting after successful completion of reviews

Customised reports

Murzilli Consulting is able to create customised, comprehensive reports for the drone and advanced air mobility industries. Our team of experts can cover nearly every aspect of the industry, including reports exploring the best pathway to market, drone and UTM/U-space regulations, and innovative technology solutions, among others.

Our reports are based on extensive research and are both written and reviewed by industry experts to ensure accuracy and reliability. Our technical editor also guarantees that our reports meet the highest quality standards.



With our reports you will:

- •Gain a competitive advantage through reports covering the latest regulatory trends and developments in the drone industry that are relevant to your organisation
- •Make informed decisions based on customised insights to your industry-specific needs that empower you to align your organisational strategy with present and future opportunities
- •Identify new markets and revenue stream through our insider experts specialised in your organisation's area of expertise
- •Evaluate the potential impact of new technologies or regulatory changes on your organisation

Services





Training



Murzilli Consulting has an established partnership with DroneTalks.online to provide educational training (both remote and in person) to aviation professionals.

Our current trainings include:

- **1. Regulatory training:** a two-day training covering modern regulatory frameworks from EASA, FAA and touching on global regulations. The level of complexity for this training is customised to the professionals taking it.
- **2. Specific operations risk assessment (SORA) training:** a two-day training covering the SORA framework, including practical examples and educational materials. The level of complexity for this training is customised to the professionals taking it.
- 3. Special request: do you have a specific training in mind for your organisation, but aren't sure where to find an expert? Our network consists of world-renowned aviation experts, so it's likely that we would be able to facilitate the training for you. Please send a detailed request to the DroneTalks team with more information, and we will get back to you.



More information:



Services



Other aviation consulting matters





Didn't find what you were looking for?

If you have a specific consulting request for the Murzilli Consulting team, please give us a call or book a meeting with our team where we can create a consulting package tailored to your organisation's needs.

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