Bridge&Flow
Independent product development and regulatory consultant

# SELECTED PROJECT EXPERIENCE

Product Development • Formulation
Regulatory Strategy • Market Readiness

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*For confidentiality reasons, client names and commercially sensitive details are anonymized.*

# TABLE OF CONTENTS

01 Profile & Working Method 3-7

02 Product Development & Formulation 8-20

03 Regulatory & Quality Projects 21-28

04 Additional Experience & Contact 29

09 Aromatic consumer product - market strategy

11 Portable hygiene spray - strategic discovery

12 Functional confectionery prototype strategy

13 Whitening tooth powder

14 Three-product body ritual

15 Moisturizing body oil

16 Natural balm troubleshooting

17 Baby talc powder - US market

18 Aromatic roll-on - formula, CPSR support & PIF

19 Zero-calorie syrup

20 Plant-based protein powder

22 EPA biological seed treatment

23 US import & MoCRA portfolio strategy

24 EU MDR Class I & EUDAMED

25 FSSC 22000 feasibility

26 EU/UK PPE market placement

27 EU setup & CPP strategy for MENA

28 Label, claims & scientific content review

*Selected freelance project examples. Client details anonymized.*

Bridge&Flow
Regulatory. Product Development. Formulation.

# ABOUT ME

I help startups and growing companies move from product idea to a practical path toward prototype, manufacturing and market entry.

My work combines product development, formulation and regulatory strategy. I can support early feasibility, structure the project, review ingredients, prepare technical documents, and help the transition to a lab or manufacturer.

I work directly with each client as the main point of contact. I work independently, not through an agency. I can support early bench work from my small product-development lab to create and test samples. When external validation, specialized testing, or scale-up is required, I coordinate trusted partner laboratories and experts.

### Product development

Concept review, feasibility, roadmaps and prototype planning.

### Formulation

Cosmetics, consumer products, food, oral care and supplements.

### Regulatory strategy

US, Canada, EU and UK market access and documentation.

### Technical delivery

Reports, briefs, SOPs, CPSR/PIF support and label reviews.

Cosmetics | Food & Supplements | Medical Devices | Consumer Products

United States | Canada | European Union | United Kingdom | MENA

*Selected freelance project examples. Client details anonymized.*

# EDUCATION & PROFESSIONAL TRAINING

## University of Pennsylvania

Regulatory Compliance Specialization

## Johns Hopkins University

Toxicology Certificate

### SELECTED CONTINUOUS PROFESSIONAL TRAINING

- US FDA and MoCRA
- Health Canada
- EU Cosmetic Regulation
- Medical Device Regulation (EU MDR)
- ISO 13485
- ISO 22000 / HACCP
- FSSC 22000
- ISO 14000
- REACH and CLP
- Cosmetic Product Safety Assessment

## How this supports client projects

My background allows me to connect formulation, toxicology, quality systems and market requirements instead of treating each topic separately.

*Selected freelance project examples. Client details anonymized.*

# HOW I SUPPORT PRODUCT DEVELOPMENT PROJECTS

## Product development

- Concept review and positioning
- Technical feasibility assessment
- Development roadmap
- Prototype strategy

## Formulation

- Ingredient selection
- Formula development or review
- Stability and compatibility evaluations
- Laboratory brief preparation

## Regulatory & market access

- Classification and pathway strategy
- Claims and label review
- FDA / Health Canada / EU / UK support
- CPSR, PIF and technical documentation

## Manufacturing & quality

- Process recommendations
- SOPs and transfer documents
- Supplier / laboratory coordination
- Quality system and certification readiness

WORKING STYLE

Practical • Direct communication • Fixed-price milestones when useful
Small-lab bench support • Partner-lab coordination

*Selected freelance project examples. Client details anonymized.*

# REPRESENTATIVE DELIVERABLES

01

## Product development roadmaps

*Client-ready, practical and structured*

02

## Technical feasibility assessments

*Client-ready, practical and structured*

03

## Formulation briefs

*Client-ready, practical and structured*

04

## Formula options and ingredient rationale

*Client-ready, practical and structured*

05

## Regulatory gap assessments

*Client-ready, practical and structured*

06

## CPSR and PIF support

*Client-ready, practical and structured*

07

## Label and claims reviews

*Client-ready, practical and structured*

08

## SOPs and process instructions

*Client-ready, practical and structured*

09

## Manufacturing and market access plans

*Client-ready, practical and structured*

*Selected freelance project examples. Client details anonymized.*

# INDUSTRIES, MARKETS & APPROACH

## INDUSTRIES

- Cosmetics
- Oral Care
- Dietary Supplements
- Medical Devices
- Agricultural Biologicals
- Consumer Products
- Food & Beverages
- Functional Foods
- Aromatic Products

## MARKETS

- European Union
- United Kingdom
- United States
- Canada
- MENA markets

## MY APPROACH

1. **UNDERSTAND** — objectives & constraints
2. **ANALYZE** — technical & regulatory
3. **DEVELOP** — concept or formula
4. **VALIDATE** — testing & documentation
5. **TRANSFER** — lab or manufacturer
6. **SUPPORT** — launch & improvement

**I combine product development, formulation and regulatory strategy**
to reduce technical risk and help clients make better decisions before they spend more.

*Selected freelance project examples. Client details anonymized.*

# PRODUCT DEVELOPMENT & FORMULATION

From early concept to a clear prototype and manufacturing path.

**Selected examples**

Consumer products • Cosmetics • Food • Oral care

Case Study 01

# Aromatic Consumer Product - Market Strategy

Product Development • Formulation • Regulatory Direction

Client anonymized | North American consumer-product concept

## 1 Client need

- Develop a premium aromatic product inspired by traditional formats without making a direct copy.
- Build a first formula direction while keeping a non-therapeutic consumer-product position.
- Prepare a prototype, stability and scale-up roadmap.

## 2 What I delivered

- Technical review and benchmark
- Raw-material and ingredient relevance review
- First V1 formula direction
- Ingredient rationale and formulation brief
- Prototype, testing and laboratory roadmap

## 3 Outcome

The work moved the project from a broad idea to a controlled development plan, with the main formulation and regulatory risks visible before laboratory investment.

### ILLUSTRATIVE DEVELOPMENT SCOPE

1. **Technical review**
   Review available research, constraints and benchmark products.
2. **Ingredient strategy**
   Define ingredient functions, sourcing criteria and decision points.
3. **V1 formula direction**
   Prepare a first structured direction for prototype development.
4. **Prototype roadmap**
   Set testing, stability and laboratory priorities.
5. **Regulatory position**
   Keep the concept within the intended consumer-product pathway.

*Portfolio mock-up based on an anonymized project structure. No client document or proprietary formula is shown.*

**KEY EXPERTI** Product Development • Formulation • North American Market Strategy • Ingredient Selection • Lab Coordination

# AROMATIC PRODUCT - DEVELOPMENT PACKAGE

*Selected proof of work - anonymized*

## INGREDIENT SELECTION MATRIX (EXTRACT)

| Ingredient | Function | Technical note |
|---|---|---|
| Cooling aromatic | Sensory | Supports fresh opening |
| Botanical oil | Fragrance | Adds depth and evolution |
| Mentholated note | Cooling | Requires concentration control |
| Carrier material | Support | Controls release and stability |
| Optional accent | Differentiation | Prototype comparison |

## FORMULATION CONCEPT - V1 (EXTRACT)

| Phase | Purpose | Target range |
|---|---|---|
| Base | Aromatic support | q.s. to 100% |
| Cooling system | Freshness / impact | Defined after test |
| Botanical blend | Signature profile | Prototype range |
| Stability support | Release control | As needed |
| Optional variant | Sensory comparison | Testing only |

## REGULATORY DIRECTION MAP

1 **Consumer product path**
Sensory / aromatic experience
No health or respiratory claims

2 **Future NHP path**
Separate SKU and evidence package
Only if therapeutic positioning is intended

Case Study 02

# Portable Hygiene Spray - Strategic Discovery

Strategic Product Development • Project Structuring

Client anonymized | Consumer cleaning concept

## 1 Client need

- The project first appeared to be a formulation request.
- The real need was broader: validate the product strategy before spending on lab work, packaging and manufacturing.
- The concept had to remain scalable across several markets and future formats.

## 2 What I delivered

- Fixed-price discovery phase
- Technical and commercial feasibility review
- Packaging and manufacturing direction
- Regulatory and claims strategy
- Development milestones and budget logic

## 3 Outcome

This reframed the work from "just formulation" into a real product-development program and gave the client a stronger decision base before larger investment.

### PROJECT SNAPSHOT


### MY ROLE

- Challenged the project assumptions before formulation.
- Connected target cost, packaging, supply chain, regulatory positioning and manufacturing constraints.

**KEY EXPERTISE** Product Strategy • Feasibility • Manufacturing • Packaging • Regulatory Strategy

Case Study 03

# Functional Confectionery Prototype Strategy

Food Innovation • Prototype Strategy

Client anonymized | Functional confectionery concept

## 1 Client need

- Assess whether a target functional dose could be delivered in a soft, pleasant confectionery format.
- Create a physical-prototype path rather than stopping at a written formula.
- Keep future lower-dose variants possible without developing every SKU at once.

## 2 What I delivered

- Product brief and SKU roadmap
- Texture, release and sensory targets
- Prototype and sample objective
- Packaging and stability questions
- Manufacturing and regulatory checkpoints

ILLUSTRATIVE SKU ROADMAP

01 **Lead SKU**
Primary target dose
Prototype first

02 **Variant A**
Lower target dose
Evaluate after lead SKU

03 **Variant B**
Mini format
Future extension

*Exact dosage targets and commercially sensitive parameters are withheld.*

*Illustrative SKU roadmap - anonymized*

## 3 Outcome

The client received a focused lead-SKU strategy and a clear route toward physical samples within the intended timeline.

KEY EXPERTISE Food Development • Prototype Strategy • Functional Ingredients • Manufacturing

Case Study 04

# Peroxide-Free Whitening Tooth Powder

Formulation Review • Regulatory Risk Assessment

Client anonymized | Oral-care product

## 1 Client need

- Compare a baseline whitening-powder formula with a more complex enzyme-based option.
- Understand the effect of formula complexity on stability, safety assessment and claims.
- Select the most efficient route to market.

## 2 What I delivered

- Two formula options
- Side-by-side technical comparison
- Ingredient rationale
- Stability and claims comments
- Clear recommendation for the preferred path

## 3 Outcome

The baseline option was recommended as the more robust and efficient first route, while the enzyme option remained available for later differentiation.

### FORMULATION OPTIONS - ANONYMIZED EXTRACT

| OPTION A - BASELINE | | OPTION B - ENZYME | |
|---|---|---|---|
| Calcium-based abrasive | Primary polishing | Adjusted abrasive base | Lower alkalinity |
| Sodium bicarbonate | Buffer / cleaning | Papain + bromelain | Protein-film breakdown |
| Micro-hydroxyapatite | Remineralising support | Encapsulated PAP | Whitening |
| PAP system | Peroxide-free whitening | Moisture control | Critical for stability |
| Mild surfactant | Foaming | Additional warnings | Safety / sensitivity |

**RECOMMENDATION**

Start with Option A for a lower-complexity and more predictable path to market.

**KEY EXPERTI** Oral Care • Powder Formulation • Ingredient Selection • Cosmetic Safety Documentation

Case Study 05

# Three-Step Body Ritual Collection

Cosmetic Product Architecture • Laboratory Briefs

Client anonymized | Premium body-care concept

## 1 Client need

- Create a coherent three-product ritual where each step prepares the skin for the next.
- Combine enzymatic, mechanical and oil-based technologies without losing consumer clarity.
- Give a laboratory enough technical direction to begin development.

## 2 What I delivered

- Activating biotech cleanser brief
- Oil-to-milk body polish brief
- Lightweight glow-oil brief
- Target ingredients and percentages
- Lab-ready product and sensory direction

## 3 Outcome

The client received a connected product system rather than three isolated ideas, with clear development logic for the laboratory.

THREE LAB BRIEFS

01 **Activating cleanser**
Enzymes + PHA
Role: Prepare

02 **Reaction body polish**
Oil-to-milk + exfoliation
Role: Transform

03 **Liquid glow veil**
Dry oils + barrier actives
Role: Seal

KEY EXPERTISE Cosmetic R&D • Range Architecture • Formula Briefs • Sensory Design

*Selected freelance project examples. Client details anonymized.*

Case Study 06

# Moisturizing Body Oil - Two Formula Directions

Cosmetic Formulation • Product Positioning

Client anonymized | Body-care brand

## 1 Client need

- Review an existing body-oil concept while preserving the brand's natural positioning.
- Improve absorption, skin feel, stability and retail readiness.
- Offer a practical choice instead of one vague formula direction.

## 2 What I delivered

- Option 1: fully botanical oil base
- Option 2: lighter dry-touch version
- Exact formula percentages
- Manufacturing instructions
- INCI and claims guidance
- Line-extension ideas

### ANONYMIZED FORMULATION SUMMARY

Two formula directions prepared for manufacturer review and validation

#### OPTION 1 - BOTANICAL DIRECTION

- Plant-oil architecture with a richer, nourishing sensory profile.
- Botanical story supported by antioxidant protection and a simple INCI direction.
- Complete formula, manufacturing sequence and implementation notes delivered to the client.

#### OPTION 2 - DRY-TOUCH DIRECTION

- Lighter carrier architecture designed for faster absorption and reduced transfer.
- Improved spreadability and a more retail-ready finish for broader consumer appeal.
- Technical recommendations linked formula performance, positioning and future line extensions.

**CONFIDENTIALITY NOTE**

Exact ingredient percentages and commercially sensitive formulation details are withheld.

Anonymized formulation and product-positioning summary

## 3 Outcome

The client could choose the right balance between botanical identity, user experience and a more retail-ready finish.

**KEY EXPERTISE** Cosmetic Formulation • Body Oils • Sensory Optimizatio Manufacturer Readiness

Case Study 07

# Natural Balm - Gritty Texture Diagnosis

Troubleshooting • Process Control • SOP

Client anonymized | All-natural topical balm

## 1 Client need

- A balm showed a recurring gritty or crystalline texture after cooling and storage.
- The client needed a targeted fix without changing the whole natural product concept.
- The defect had already persisted through several formula tests.

## 2 What I delivered

- Root-cause diagnosis report
- Corrective action plan
- Melting, menthol and pour-temperature controls
- Critical cooling parameters
- Short manufacturing SOP
- Quality checks at 24 h, 72 h and 1-2 weeks

### ANONYMIZED PROCESS-CONTROL SUMMARY

Root-cause diagnosis and corrective plan

#### ROOT CAUSE

- The defect was identified as post-pour crystallization rather than incomplete melting or poor mixing.
- Likely contributors included fat polymorphism, rapid temperature change, crystallizing-active load and unstable storage conditions.

#### CORRECTIVE DIRECTION

- Control melting and holding conditions.
- Confirm complete dissolution before cooling.
- Use a defined pour window and gradual ambient cooling.
- Hold samples before texture release and storage evaluation.

#### DELIVERABLES

- Root-cause report
- Corrective action plan
- Short manufacturing SOP
- Quality checks over time

Detailed set-points and formulation parameters are withheld.

Anonymized technical diagnosis and process-control summary

## 3 Outcome

The problem was treated as a process-control issue, allowing the client to correct the defect without a complete reformulation.

KEY EXPERTISE Troubleshooting • Anhydrous Balms • Process Development • SOP Writing

Case Study 08

# Baby Talc Powder - US Market

Baby Care • Powder Formulation • US Cosmetics

Client anonymized | Baby-care cosmetic

## 1 Client need

- Develop a gentle baby talc powder for the US market.
- Balance absorbency, smooth application, powder flow and low-dust handling.
- Integrate baby-specific safety and label considerations early.

## 2 What I delivered

- Prototype-ready formula direction
- Ingredient-function rationale
- Manufacturing sequence
- Packaging and dust-control considerations
- US cosmetic label and safety checkpoints

FORMULATION FRAMEWORK

**Powder base**
Absorbency and slip

**Texture modifier**
Soft, non-gritty skin feel

**Flow support**
Consistent filling and dispensing

**Fragrance - optional**
Conservative baby-care direction

**Packaging**
Controlled application and dust reduction

Key design point: control airborne dust and foreseeable inhalation exposure.

## 3 Outcome

The project produced a clear formulation foundation and a practical prototype/testing path for a baby-care powder intended for US commercialization.

KEY EXPERTISE Baby Care • Powder Formulation • US Cosmetics • Safety-by-Design

Case Study 09

# Aromatic Roll-On - Formula, CPSR Support & PIF

Cosmetic Formulation • EU Safety Documentation

Client anonymized | Leave-on aromatic roll-on

## 1 Client need

- Develop an anhydrous aromatic roll-on and support EU market readiness.
- Connect the formula, packaging, intended use and safety documentation.
- Prepare a complete technical file for the Responsible Person.

## 2 What I delivered

- Final formulation and ingredient-documentation review
- CPSR preparation support, including Part A compilation and coordination of information required for Part B
- Product Information File support under Article 11
- Manufacturing method and GMP section
- Warnings, use conditions and packaging notes

## 3 Outcome

The project delivered a connected formulation and regulatory package rather than separate documents, supporting the Responsible Person's pre-launch review.

### FORMULATION OVERVIEW

| INCI name | Function | Indicative level |
|---|---|---|
| Carrier oil (unspecified) | Carrier | q.s. |
| Aromatic component (unspecified) | Fragrance | < 2% |
| Essential oil blend (unspecified) | Fragrance | < 1% |
| Antioxidant (unspecified) | Antioxidant | Trace |
| Component (unspecified) | Skin conditioning | < 2% |

*Note: Levels are indicative ranges and may vary within formulation constraints. Exact composition is held on file.*

### DOCUMENTATION & SAFETY SUMMARY

The following documents and support were prepared and compiled:

- Safety Data Sheet (SDS) review
- IFRA compliance statements
- Allergen declarations
- Raw material specifications
- Safety evaluation support and CPSR coordination

*Anonymized formulation and safety summary*

KEY EXPERTISE Cosmetic Formulation • CPSR Support • PIF • Essential Oils • EU Regulation

Case Study 10

# Zero-Calorie Syrup - Hazelnut Flavor

Food Formulation • Target Specification

Client anonymized | Barista syrup line

## 1 Client need

- Develop a sugar-free, zero-calorie flavored syrup for coffee, beverages and desserts.
- Control taste, viscosity, preservation and separation while keeping a simple ingredient system.
- Prepare production and label specifications for EU/UK commercialization.

## 2 What I delivered

- Formulation and ingredient system
- Organoleptic criteria
- Proposed physicochemical and microbiological targets
- Nutrition and allergen information
- Packaging, storage and shelf-life validation plan
- Label-content checklist

## 3 Outcome

The client received a target product specification connecting formula design with the testing and quality work required before commercialization.

### TARGET PRODUCT SPECIFICATION

**Zero-calorie hazelnut syrup - development draft**

#### 1. PRODUCT PROFILE

Clear, hazelnut-flavored syrup proposed for coffee, beverages and dessert applications.

#### 2. TARGET SENSORY PROFILE

| | |
|---|---|
| **Appearance** | Clear; no visible particles |
| **Aroma** | Characteristic hazelnut profile |
| **Taste** | Sweet, balanced, clean finish |
| **Aftertaste** | Target: minimal off-notes |

#### 3. DEVELOPMENT TARGETS

| | |
|---|---|
| **pH** | Target range to be confirmed |
| **Soluble solids** | Target range to be confirmed |
| **Viscosity** | Target range to be confirmed |
| **Microbiology** | To be confirmed by qualified testing |

#### 4. PACKAGING & STABILITY

Proposed PET or HDPE formats are subject to packaging compatibility review.

Shelf life is a development target only and must be established through formal stability testing in final packaging.

#### VALIDATION NOTE

All values shown are development targets subject to formulation, laboratory, packaging, stability and production validation.

*Illustrative target specification - anonymized*

KEY EXPERTISE Food Formulation • Zero-Calorie Products • Target Specifications • EU/UK Food Labelling

Case Study 11

# Plant-Based Protein Powder - US & Canada

Food Product Development • Label & Claims Review

Client anonymized | Plant-based nutrition brand

## 1 Client need

- Support two plant-based protein powders intended for sensitive consumers.
- Review the formula, low-FODMAP positioning, claims and labels for US and Canadian markets.
- Prepare clear bilingual corrections for implementation.

## 2 What I delivered

- FDA and Health Canada review report
- Annotated label mark-ups
- English/French ingredient and allergen text
- Claims and founder-story corrections
- Canadian Nutrition Facts requirements
- Final compliance checklist

## 3 Outcome

The client received copy-ready corrections and a specific implementation path for both the US and Canadian versions.

LABEL REVIEW - ANONYMIZED MOCK-UP

**PLANT-BASED PROTEIN POWDER**

| | |
|---|---|
| LOW-FODMAP* | Certification required |
| EASY TO DIGEST | Revise implied benefit |
| ZERO GUT TRIGGERS | Avoid absolute claim |
| 20 g PROTEIN | Verify per serving |

CANADA ACTIONS

- Bilingual identity and ingredients
- Canadian Nutrition Facts table
- English/French allergen statement

KEY EXPERTISE Protein Powders • FDA Food • Health Canada • Bilingual Labelling • Claims Review

# REGULATORY & QUALITY PROJECTS

Market access, technical documentation, quality systems and claims.

**Selected examples**

FDA • Health Canada • EU MDR • PPE • FSSC 22000 • MENA

Case Study 12

# EPA Registration Pathway - Biological Seed Treatment

Regulatory Strategy • EPA Submission Readiness

Client anonymized | Agricultural biological product

## 1 Client need

- Validate whether the proposed EPA end-use-product pathway was structurally sound.
- Review alignment between the application strategy, label scope, formulation documents and reliance materials.
- Then assess whether the updated submission package looked ready to proceed.

## 2 What I delivered

- Phase 1: pathway validation
- Phase 2: submission-readiness review
- Technical / MUP / EP alignment
- CSF and label consistency check
- Crop-scope and claim-wording review

## 3 Outcome

The work clarified the registration logic, reduced avoidable inconsistencies and supported a more coherent first-submission strategy.

**TWO-STEP REGULATORY REVIEW**

1 **PHASE 1 - PATHWAY VALIDATION**

Structural logic, reliance basis, forms and label alignment.

2 **PHASE 2 - SUBMISSION READINESS**

Updated label scope, Technical/MUP/EP chain and CSF consistency.

**RESULT**

A clearer, more coherent first-submission package.

**KEY EXPERTISE** EPA • Biopesticides • Label Strategy • Submission Readiness

*Selected freelance project examples. Client details anonymized.*

Case Study 13

# US Import & MoCRA Portfolio Strategy

FDA / CBP • Import Structure • Broker Handoff

Client anonymized | Multi-product cosmetic portfolio

## 1 Client need

- A diverse portfolio of raw materials, finished cosmetics, DIY kits and accessories was moving to a new US Importer of Record.
- The client needed to understand where import sensitivity could arise before any formal blockage.
- Mixed-pallet classification logic also had to be made clearer for the customs broker.

## 2 What I delivered

- Portfolio-level FDA / MoCRA review
- Structural risk and sensitivity table
- Pallet segmentation by product family
- Classification logic notes without assigning HTS codes
- Broker-facing handoff document

## 3 Outcome

The work explained why questions could arise even without non-compliance and gave the broker a cleaner basis for pre-clearance and future pallets.

**ILLUSTRATIVE PORTFOLIO STRUCTURE**

| Line | Product family | Product type | Review focus |
|---|---|---|---|
| A-01 | Finished cosmetics | Finished product | Label / compliance |
| A-02 | Cosmetic ingredients | Raw material | Identity / documents |
| A-03 | Component kit | Multi-component set | Classification logic |
| A-04 | Accessories | Non-cosmetic item | Product category |
| A-05 | Intermediate material | Semi-processed | Processing status |

**Purpose**

Separate product families, identify sensitive lines and prepare a clearer broker handoff.

*Illustrative mock-up created for portfolio display. It is not a client invoice, product list or customs document.*

*Pallet segmentation matrix - illustrative and anonymized*

**KEY EXPERTISE** FDA • MoCRA • Import Compliance • Portfolio Strategy • Broker Coordination

Case Study 14

# Class I Medical Device - EU MDR & EUDAMED

Medical Device Regulatory • EU Market Access

Client anonymized | Non-sterile skin-contact patch

## 1 Client need

- Confirm EU classification for a non-sterile, non-measuring Class I device.
- Review the technical-documentation package and legal manufacturer / EU representative structure.
- Clarify the registration and labeling path before market entry.

## 2 What I delivered

- Classification conclusion under MDR (EU) 2017/745
- Manufacturer and EU authorised representative configuration
- EUDAMED registration support points
- Claims and multilingual label review
- Technical-documentation gap observations

## 3 Outcome

The project clarified the route to EU placement without a notified body and reduced confusion around roles, registration steps and documentation expectations.

**EU MDR – Class I Registration Summary**

**1. Regulatory conclusion**

Based on the information provided, the device is classified as Class I under MDR (EU) 2017/745.

- Non-sterile
- Non-measuring
- Non-invasive
- No active device function
- No Notified Body involvement required

The device can be placed on the EU market once the manufacturer complies with all applicable MDR requirements.

**2. Manufacturer and EU authorised representative considerations**

- Maintain valid quality management system and technical documentation.
- Act as the legal manufacturer and assume full regulatory responsibility.
- Appoint an EU authorised representative before placing the device on the EU market.

**3. Registration pathway**

Register the manufacturer and the device in EUDAMED (Actor, SRN, and UDI-DI as applicable) prior to market placement.

- Ensure data accuracy and consistency across modules.
- Maintain registration information throughout the product lifecycle.

**4. Labeling observations**

Labeling should comply with MDR Annex I and all applicable requirements.

- Include mandatory information and symbols.
- Ensure instructions for use are available to end users.
- Verify multilingual labeling for target markets.

*Anonymized regulatory conclusion summary*

KEY EXPERTISE EU MDR • Class I Devices • EUDAMED • UDI • Technical Documentation

Case Study 15

# FSSC 22000 Certification Feasibility

Food Safety • Certification Readiness

Client anonymized | Food importer and distributor

## 1 Client need

- Determine whether FSSC 22000 was the right route for a company serving premium food-service customers.
- Clarify category, applicability, budget and workload before engaging a certification body.
- Avoid a premature certification attempt.

## 2 What I delivered

- Certification-route feasibility assessment
- Category and applicability analysis
- Readiness-gap review
- Certification-body cost indications
- Implementation roadmap and next-step recommendation

## 3 Outcome

FSSC 22000 was confirmed as commercially relevant, but the client also gained a realistic view of the system, cost and internal preparation required first.

### FSSC 22000 Feasibility Summary

**Objective**

Determine whether FSSC 22000 is the right certification route based on business goals, customer requirements and operational context.

**Applicability**

FSSC 22000 is applicable to the company's activities within the food supply chain and aligns with key customer and market requirements.

**Readiness Observations**

- Food safety management system in place with defined scope and policies
- Most prerequisite programs established; select areas need strengthening
- Documented procedures and records require further alignment
- Internal audits and management reviews need more consistency

**Cost and Workload Considerations**

- Certification and audit costs estimated within typical market range
- Implementation effort is moderate with current resources
- Timeline to certification estimated at 6–9 months with focused execution

**Recommendation**

Proceed with FSSC 22000 certification after addressing identified gaps. Begin with a defined improvement plan and consider a certification body with relevant category experience.

*Anonymized executive summary excerpt*

KEY EXPERTISE FSSC 22000 • Food Safety • Gap Assessment • Certification Strategy

Case Study 16

# EU & UK PPE Market Placement - Solar Products

PPE Regulation • Product Classification • User Information

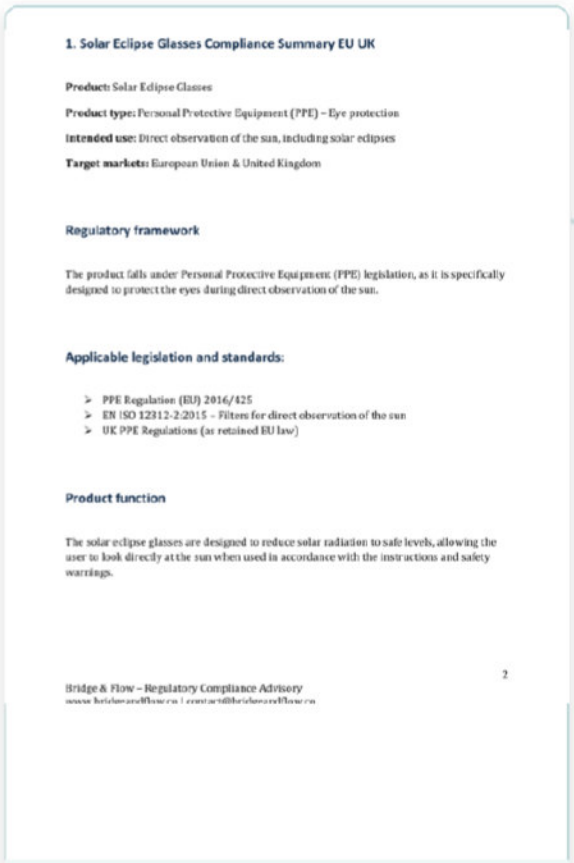
Client anonymized | Solar-viewing products

## 1 Client need

- Assess solar eclipse glasses and a separate smartphone camera filter for EU and UK market placement.
- Keep the eye-protection product under PPE rules while clearly separating the non-PPE accessory.
- Review warnings, artwork and multilingual user-information strategy.

## 2 What I delivered

- PPE compliance summary
- EN ISO 12312-2 positioning
- Artwork and mandatory-warning review
- QR-based user instructions
- EU language matrix
- Separate non-PPE regulatory statement for the camera filter



**1. Solar Eclipse Glasses Compliance Summary EU UK**

**Product:** Solar Eclipse Glasses

**Product type:** Personal Protective Equipment (PPE) – Eye protection

**Intended use:** Direct observation of the sun, including solar eclipses

**Target markets:** European Union & United Kingdom

**Regulatory framework**

The product falls under Personal Protective Equipment (PPE) legislation, as it is specifically designed to protect the eyes during direct observation of the sun.

**Applicable legislation and standards:**

- PPE Regulation (EU) 2016/425
- EN ISO 12312-2:2015 – Filters for direct observation of the sun
- UK PPE Regulations (as retained EU law)

**Product function**

The solar eclipse glasses are designed to reduce solar radiation to safe levels, allowing the user to look directly at the sun when used in accordance with the instructions and safety warnings.

Bridge & Flow – Regulatory Compliance Advisory

2

*PPE compliance excerpt - anonymized*

## 3 Outcome

The client received a clear route for market placement and a practical multilingual-information system without confusing the accessory with eye protection.

**KEY EXPERTISE** PPE Regulation • EU/UK Market Access • Artwork Review • Technical Instructions

Case Study 17

# EU Setup & CPP Strategy for MENA Expansion

Pharmaceutical Strategy • International Market Access

Client anonymized | MENA registration strategy

## 1 Client need

- Build an EU structure capable of supporting CPP-driven registrations in MENA markets.
- Compare jurisdictions without reducing the decision to a simple country choice.
- Consider MA transfer, market presence, governance and operational sustainability.

## 2 What I delivered

- Initial strategy framework
- EU-jurisdiction comparison criteria
- MA transfer and CPP considerations
- Risk sequencing
- Operational and governance requirements
- Recommended direction for detailed assessment

Based on what you shared, the question is not only about choosing between Sweden and another EU jurisdiction such as the Netherlands. It is really about setting up a structure that will reliably support your registrations in MENA, especially for Iraq, while remaining workable in practice from both a regulatory and operational perspective.

What makes this topic more complex in your case is the combination of a CPP-driven strategy, a potential MA transfer, and the use of a "dummy launch" approach. Each of these elements can work individually, but the difficulty is making sure they remain consistent and acceptable when combined into a single setup.

In practice, one of the key questions will be how the CPP is actually generated and perceived. A setup that is technically valid at EU level can still raise questions at local authority level if the underlying market presence is seen as too limited or not sufficiently substantiated. This is typically where strategies based on minimal or artificial market placement start to lose robustness.

In your case, this creates a fairly clear trade-off between speed and sustainability. It is possible to design a setup that allows relatively quick CPP generation, but this does not always translate into a structure that will hold when reviewed more closely or when extended to additional markets. On the other hand, a more grounded setup may take slightly longer to establish but tends to be more reliable over time.

This is particularly relevant for markets like Iraq, where the way CPPs are reviewed and validated in practice does not always follow a purely formal logic. In these situations, the overall credibility of the setup tends to matter as much as the formal compliance of each individual component. This is often where "borderline" strategies become difficult to defend.

Another point to consider is the MA transfer and how it interacts with the chosen jurisdiction. Beyond timelines, this has implications on how much control you retain over the dossiers, how easily variations can be managed, and how flexible the structure remains as you expand into other MENA markets.

There is also a sequencing aspect that becomes important here. The order in which the MA transfer, CPP generation, and market entry are handled can significantly impact both timelines and regulatory acceptability. A setup that is theoretically sound can still create delays or inconsistencies if these steps are not aligned properly.

At the same time, the operational implications should not be overlooked. Establishing or relocating a MAH comes with concrete requirements in terms of pharmacovigilance, QMS, and ongoing maintenance. These are not just formal obligations, they directly shape what is realistically manageable once the structure is in place.

2

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*Strategy framework excerpt - anonymized*

## 3 Outcome

The client gained a stronger decision framework focused on a sustainable EU setup rather than a short-term "dummy launch" solution.

**KEY EXPERTISE** Pharma Strategy • CPP • EU Setup • MENA Market Access • Risk Sequencing

# LABEL, CLAIMS & SCIENTIFIC CONTENT REVIEW

*Two representative communication-compliance projects*

## Cosmetic Label Review

**EU / UK / US**

### CLIENT NEED

- Review makeup artworks against regulatory reports and ingredient documentation.
- Resolve inconsistencies between manufacturer data, artwork and third-party reviews.

### DELIVERABLES

- EU and US label-review reports
- INCI and artwork consistency checks
- Mandatory content and claims corrections
- Manufacturer / brand action points

**ANONYMIZED COSMETIC ARTWORK**

**FRONT PANEL**

- Product identity - verify
- Net content - mandatory
- Claims - revise wording
- Responsible party - confirm

## Medical Education Content Review

**FDA / FTC communication risk**

### CLIENT NEED

- Review educational scripts and storyboards for scientific accuracy and implied claims.
- Preserve the educational value while reducing promotional or absolute language.

### DELIVERABLES

- Line-by-line script comments
- Visual-claim review
- FDA / FTC sensitivity notes
- Safer replacement wording
- Distinction between education and promotion

**STORYBOARD CLAIM CHECK**

| | | |
|---|---|---|
| ☐ | Mechanism illustration | REVIEW |
| ☐ | Safety statement | REVIEW |
| ☐ | Expected outcome | REVIEW |
| ☐ | Call to action | REVIEW |

Shared outcome: clear, defensible communication that keeps the client's message useful without creating avoidable regulatory risk.

*Selected freelance project examples. Client details anonymized.*

# ADDITIONAL SELECTED EXPERIENCE

## Cosmetics

CPSR for a hyaluronic acid face serum; beard/scalp oil fragrance-adjustment brief; international makeup label reviews.

## Food & Supplements

Nutraceutical dosage review; supplement label and claims work; food and beverage specifications.

## Medical Devices

ISO 13485 and technical-file review; GSPR review; multilingual label and user-information support.

## Consumer Products

Independent label-compliance assessment; product feasibility reviews; packaging and manufacturing roadmaps.

## Chemical / Market Access

EU chemical import and REACH pathway reviews; supplier-documentation gap assessments.

**WORKING TOGETHER**

I work directly with clients worldwide, adapting scope to the product, market and stage of development. I can support early bench work in my small lab (stability, compatibility and basic performance checks) and coordinate partner laboratories when specialized testing or scale-up is required.

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*Additional anonymized samples can be discussed when relevant to a project.*