

EISWERTH PACKAGING INTRODUCTION

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EISWERTH

— PACKAGING CONSULTING —

DESIGN • VALIDATION • COMPLIANCE

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MISSION AND VALUES

What we stand for

Mission and Values

Mission

To provide strategic packaging expertise that drives compliance, reduces risk, and accelerates time to market with a lasting impact that is felt years after implementation

Values

1. Precision & Compliance

We deliver packaging solutions that meet the highest regulatory standards, ensuring patient safety and audit readiness.

2. Practical Execution

We focus on real-world solutions that work—balancing compliance, cost, and manufacturability.

3. Ownership Mindset

We operate as an extension of your team. We succeed only when you succeed.

4. Efficiency & Speed

We help teams move faster by eliminating redundant work, reducing validation scope, and streamlining processes.

5. Integrity & Transparency

We communicate clearly, set realistic expectations, and deliver what we commit to.

WHAT WE PROVIDE

What you can expect from our services

Our Process

-Complimentary discovery phase packaging assessment free of charge-



Discovery

Assess current packaging landscape, identify gaps and risks



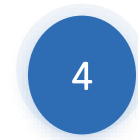
Analysis

Evaluate materials and reduce costs



Strategy

Develop tailored solutions aligned with business goals



Implementation

Execute the plan with ongoing support

What We Provide

Structure & Scaling

- Let us provide the scaffolding for your business to thrive
 - Lasting packaging infrastructure and tools felt for years to come
 - Expand company packaging knowledge and culture to scale packaging properly as it grows

Packaging Design

- Professional packaging that endures the test of time
 - Primary, secondary and tertiary packaging design utilizing latest industry trends
 - Package integrity testing including bubble leak, dye leak, and peel testing
 - 3D renderings of prototypes with artwork
 - Pallet layout design

Regulatory Assistance

- Bulletproof packaging that keeps your business safe
 - ISO11607 strategy and compliance
 - Gap analysis
 - EU MDR, FDA, and other regulatory body approval assistance
 - Worst case rationale documentation

What We Provide



Cost Savings

- Cost savings through material changes, alternative suppliers and better design



Artwork and Labeling

- Your brand is your identity. Let us build it the right way.
 - Eye popping artwork designs tailored to your brand while staying compliant and user friendly



Validation

- IQ, OQ, PQ equipment validation protocols and reports
- Implementation including training, FAI, and specification documentation
- Distribution and shelf life testing according to latest ASTM/ISTA standards



Sustainability

- Waste directive assistance for regulatory compliance
- Carbon footprint reduction

Challenges We See

What's slowing your business down?

- 1. Packaging validation delays launch**

Packaging should never prevent product launch or be an afterthought

- 2. Cost overrun**

Over-testing increases cost and timeline

- 3. Packaging is over engineered**

Packaging designs should be simple yet effective without too many custom solutions

- 4. Inconsistent packaging across SKUs**

Variability in packaging creates difficulty for sales teams and manufacturing

- 5. Audit findings and safety**

Regulatory compliance and patient safety comes first

Who Our Clients Are

- Smaller companies without the resources or need to hire a dedicated Packaging Engineer
- Large Companies that need an SME to fill a knowledge gap

Why Eiswerth Packaging?

- ✓ **Senior-level expertise without adding full-time headcount**
- ✓ **Tailored contracts either hourly or project based**
- ✓ **Extensive network of professionals consisting of graphic designers and fellow Packaging Engineers**
- ✓ **Fill internal knowledge gaps with SME help**
- ✓ **Protect your business from costly audit findings**

Project Tier Examples

Offering	Advisory	Validation	Expedited Help
Packaging Department Growth and Validation Strategy	✓	✓	✓
FDA/ISO11607/EU MDR Gap Analysis	✓	✓	✓
Packaging Design Critique	✓	✓	✓
Carton and Shipper Design with Artwork		✓	✓
Protocol and Report Creation (IQ, OQ, PQ, Distribution, Aging)		✓	✓
Equipment and Material Sourcing		✓	✓
Waste Directive and Sustainability			✓
Regulatory Readiness Assistance			✓
On-Site Validation Execution Help			✓

Pricing

- Project based pricing is based on longevity and need with longer commitments receiving a retainer rate
- Hourly rates vary based on scope of work
- Whether it's an hour a week for a phone call or close to full time commitments, Eiswerth Packaging can help

Hiring Consulting vs Full Time

Eiswerth Consulting

- ✓ **Immediate impact**

No training required with plug-and-play results

- ✓ **Senior expertise**

SME expertise from experienced Packaging Engineers and Graphic Designers

- ✓ **Flexible cost**

Costs uniquely positioned for your specific use case

- ✓ **No long-term commitment**

When the project is complete or the work is done, simply discontinue work

Hire Full-Time

- ✓ **3-6 month hiring process**

Delayed help with any project

- ✓ **Experience varies**

One person without proven track record without access to expansive network

- ✓ **Fixed salary plus benefits**

Excess costs associated with hiring someone full time

- ✓ **Long term obligation**

If the new hire isn't delivering, there is no opportunity to move on

CASE STUDY

Case Study: Preventing a Manufacturing Shutdown

Rapid packaging system transition under compressed validation timelines

< 12 Months

Timeline Risk

20+

Pouch Configurations

3

Validated Systems

Shutdown Prevented

Challenge

A critical implant pouch compatible with gas plasma sterilization was discontinued with no replacement available.

Existing inventory depletion created significant manufacturing continuity risk.

Strategic Response

Implemented a dual-path mitigation strategy:

- Replacement pouch analysis
- New tray packaging system development

Accelerated validation planning to reduce operational risk.

Execution

- Evaluated and tested 20+ pouch configurations
- Conducted IQ/OQ/PQ validation
- Coordinated suppliers and tooling
- Conducted shelf-life and distribution studies

Business Impact

- Prevented manufacturing shutdown
- Maintained production continuity
- Delivered validated packaging systems before depletion
- Reduced operational and regulatory risk



EXPERIENCE

Our background

Experience and Impact

Jonathan Eiswerth



Senior Medical Device Packaging Consultant – Founder

Bachelor of Science in Packaging Engineering – Michigan State University

8 years experience

- Emphasis on the pharma and medical device industry
- Access to network of 25+ years of experience with a team consisting of graphic designers and fellow Packaging Engineers

5000+ SKUs Packaged

- Universal, effective solutions that reduce stored packaging materials on the manufacturing floor

- | | |
|------------------------|---------------------------------|
| • Orthopedic implants | • Combination Products |
| • Surgical Instruments | • Wearables & Connected Devices |

Leadership & Ownership

Built and led packaging department
Scaled to 5,000+ SKUs
Sole SME for 5+ years

Technical Design Expertise

ISO 11607 validation (IQ/OQ/PQ)
Distribution & shelf-life
Worst-case rationale documentation
Artwork and Labeling

Regulatory Assistance

EU MDR and FDA readiness
Gap analysis

Manufacturing

Led manufacturing
Implemented packaging systems
FAI and training

Trusted to build scalable, compliant packaging systems that stand up to audit scrutiny

GETTING STARTED

How to get things moving

How to Get Started

- **Introductory Discussion**

Let's set up some time to talk

- **Complimentary Discovery Assessment**

Together we can identify where the problem areas are

- **Scope and Proposal**

Create a proposal based on what you need most

[Learn More →](#)



Let's Solve Your Packaging Challenges

Packaging should accelerate growth — **not** slow it down.

Start with a free packaging assessment

- Available for immediate consulting or contract support
- Flexible engagement (project-based or ongoing)
- Proven impact with minimal onboarding

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