



ENHANCING THE MANUFACTURE & DESIGN OF SURGICAL EQUIPMENT

IDENTIFYING NEEDS / MINIMIZING RISK

TODAY'S SPEAKER



Eric Rohr
Industry Manager, Healthcare
Color & Additives North America
Avient Corporation

Eric joined Avient through the acquisition of the Clariant Masterbatch business by PolyOne in 2020, bringing together two legacy businesses that together have a best-in-class portfolio of innovative solutions. At Avient, Eric continues to be responsible for developing solutions for the medical, pharmaceutical, and healthcare sector that meet the latest industry trends for surface functionality and aesthetics while taking into account safety and regulatory compliance.



AGENDA

- Applications and market trends
- Key considerations in surgical and medical equipment applications
- Dealing with change control
- Minimizing risk
- Healthcare industry solutions and capabilities
- Additive technologies
- About Avient

HEALTHCARE

FOCUS APPLICATIONS



**SURGICAL
EQUIPMENT**



**LABWARE /
DIAGNOSTICS**



**DRUG
DELIVERY**



**REMOTE
MONITORING**



**PHARMACEUTICAL
PACKAGING**

SURGICAL EQUIPMENT MARKET

EVOLVING TRENDS



Minimally invasive surgeries
require smaller tools



Increasing aging
population



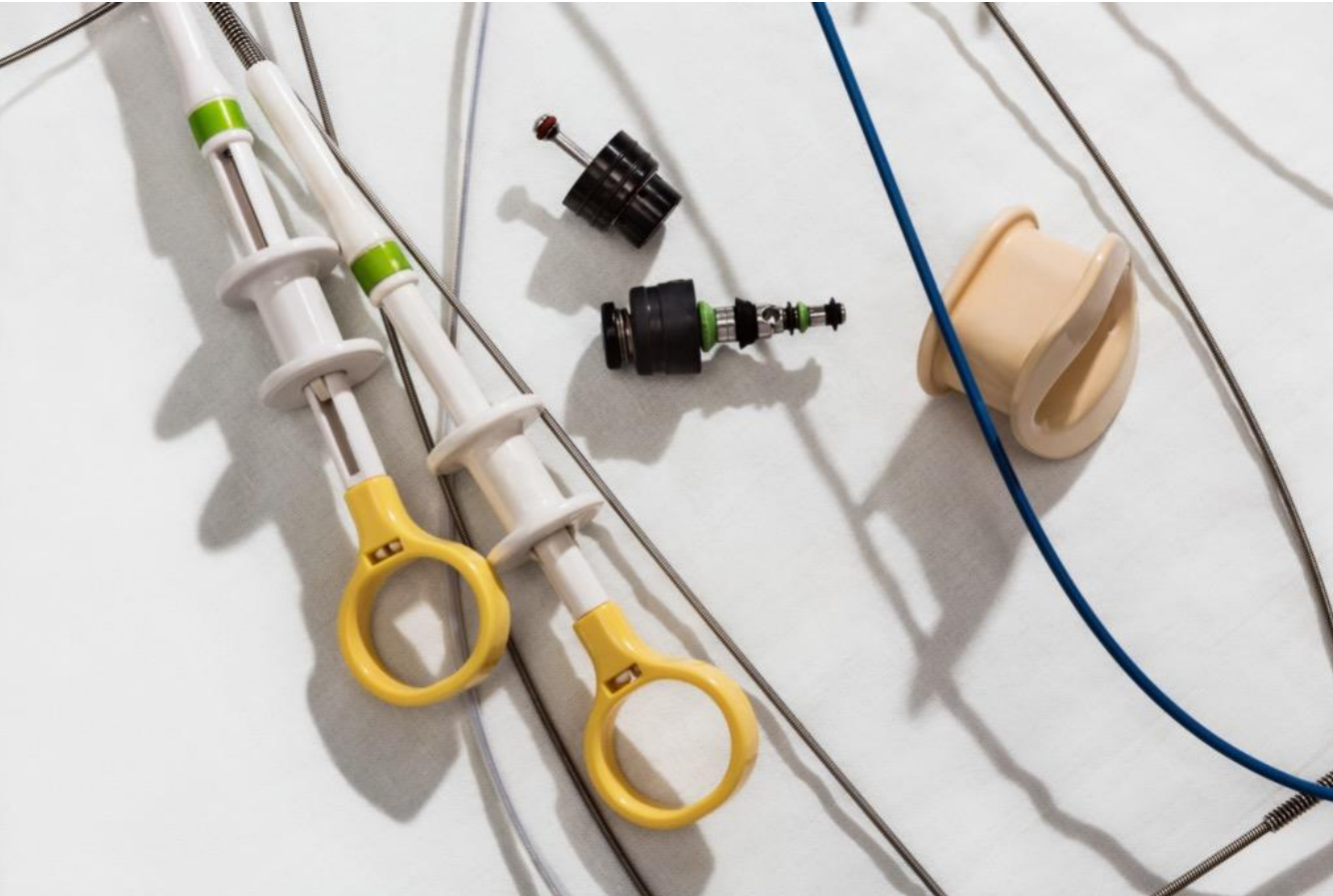
Drive to disposables and
increasing emphasis on
sustainability

*Market growth anticipated at 9% to 2025**

* Source: May 2021 BCC report "Surgical Equipment: Technologies and Global Markets"

SURGICAL EQUIPMENT PRIMARY NEEDS

KEY CONSIDERATIONS



- Medical-grade polymers
 - Regulatory compliance
 - ISO 13485 quality system
 - Biocompatibility (ISO 10993 & USP Class VI) and extractable metals
- Global presence
- Innovation
 - A supplier at the forefront of the newest technologies who understands the needs

SURGICAL EQUIPMENT PRIMARY NEEDS

FOCUS ON CHANGE CONTROL

Change control should be in place

- No unnotified change of ingredients, formulation, or process
- Consistent quality > 'device reliability & repeatability' and 'productivity'!



A CLOSER LOOK AT CHANGE CONTROL

Changes are routine in the plastics industry

- They can be an unseen and unanticipated risk to device manufacturers

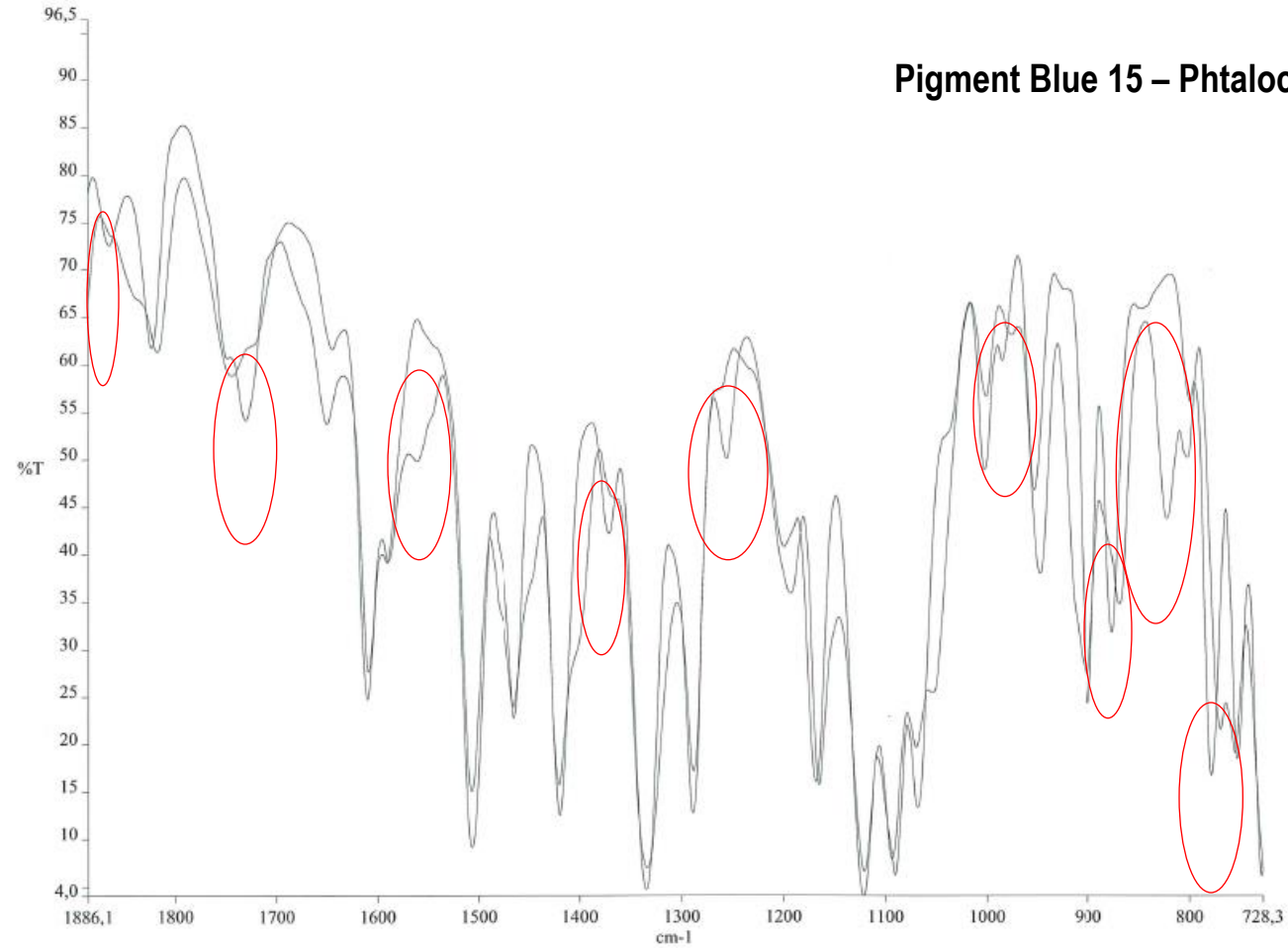
A proactive approach is needed

- Look for rigorous change controls beyond the CAS number
- Test incoming lots of raw material
- Apply controls to processes, materials, and quality systems



CHANGE EXAMPLE

PIGMENTS UNDER FTIR *



CHANGE CONTROL CONCERNS

Changes often occur

- Plant / site – industry and product consolidation driven by acquisitions and economics
- Process – catalysts, process aids, equipment, cross-contamination
- Formulation – optimization, different approaches (single pigment concentrate)
- Ingredients / supplier – price, availability (same CAS number)

Changes may result in ‘same product specification’ ...

- BUT in critical applications, more information may be needed to evaluate the change
- What is the impact on physical properties and/or E&L vs what you validated?

→ The supply chain is not always ready to fulfil the requirements of materials for healthcare applications or notify of changes ...

WHO ARE WE AND WHAT CAN WE DO

FOR SURGICAL EQUIPMENT AND BEYOND



- Avient supplies polymers and modified polymer solutions to color and enhance the properties of plastics used in medical and pharmaceutical applications
- We have global expertise in healthcare technical and regulatory requirements
- Our healthcare portfolio is manufactured according to GMP/ISO 13485 protocols on 3 continents

GLOBAL SETUP

MINIMIZE RISK AND BE
CONTROLLED, CONSISTENT, COMPLIANT



Controlled

- Look for common QMS and external ISO 13485 certification
- Segregation / line clearance
- Cleaning validation, lab validation, product validation

Consistent

- Need for harmonized product formulations for location transfers or backup
- Fingerprinting of raw materials / routine batch testing

Compliant

- Raw materials should be pre-tested to ISO 10993, USP 23 pt. 87, 88 (Class VI)
- EU Pharmacopoeia Testing (where appropriate)
- Drug & Device Masterfile listed
- Audit policy & change control agreements

PROCESSABILITY

A WIDE RANGE OF POLYMERS



- Ranging from hard polysulfones to soft TPEs
- Resin supplier agnostic

- **ABS**
- Acetal
- Acrylic
- COC
- Copolyester
- K-resin
- Nylon
- **PBT**
- **PC**
- PE
- PET
- PETG
- PP
- **PPS**
- Polyurethane
- PVC
- TPC-ET
- TPE/TPO
- TPR
- SBS
- High temperature resin
- Fluoropolymers
- + more

MEVOPUR™ FORMULATIONS

CUSTOM AND STANDARD SOLUTIONS FOR HEALTHCARE



What are they?

- Masterbatches and liquid colorants
- Standard colorant options
- Functional additives

Why are they different?

- Global network of four certified ISO 13485 manufacturing sites for security of supply
- Pre-tested raw materials to medical and pharma standards under USP Class VI and ISO 10993 biocompatibility
- Globally harmonized product formulations
- Documented change control beyond CAS number level reducing risk of change

MEVOPUR formulations are designed to help mitigate risk

WAYS WE CAN SUPPORT

CONSISTENT SOLUTIONS FOR SURGICAL EQUIPMENT

Rigorous change controls are in place with Mevopur™ products, raw materials, and processes

- Reduce risk of non-compliance
- Avoid additional re-testing costs / costs of recalls
- Minimize risk of changes that could impact product performance and reliability

Technical expertise and support

- Dedicated healthcare global technical centers

Global ISO 13485 quality systems and regulatory expertise and documentation

- Offers batch reliability and consistency
- Supports transition to new IVD Regulation



NEW TECHNOLOGIES AND COMMON ADDITIVES

- Polymer modification additive package for over-molding situations
- Laser welding – optimized absorption / transmittance
- Stabilization of radiopaque materials in PEBAX and TPU
- Friction-reduction / lubrication
- Laser marking technologies
- Anti-static / conductive
- Protection during gamma and e-beam sterilization
- Anti-microbials
- Clarifiers and nucleation agents
- Hydrophobicity and moisture control (low retention)
- Fluorine and non-fluorine high-slip chemistries

AVIENT

ABOUT US



9,700
employees
worldwide



35,000+
solutions



\$4.8 billion
in 2021 sales



\$17.5 million
donated
since 2007



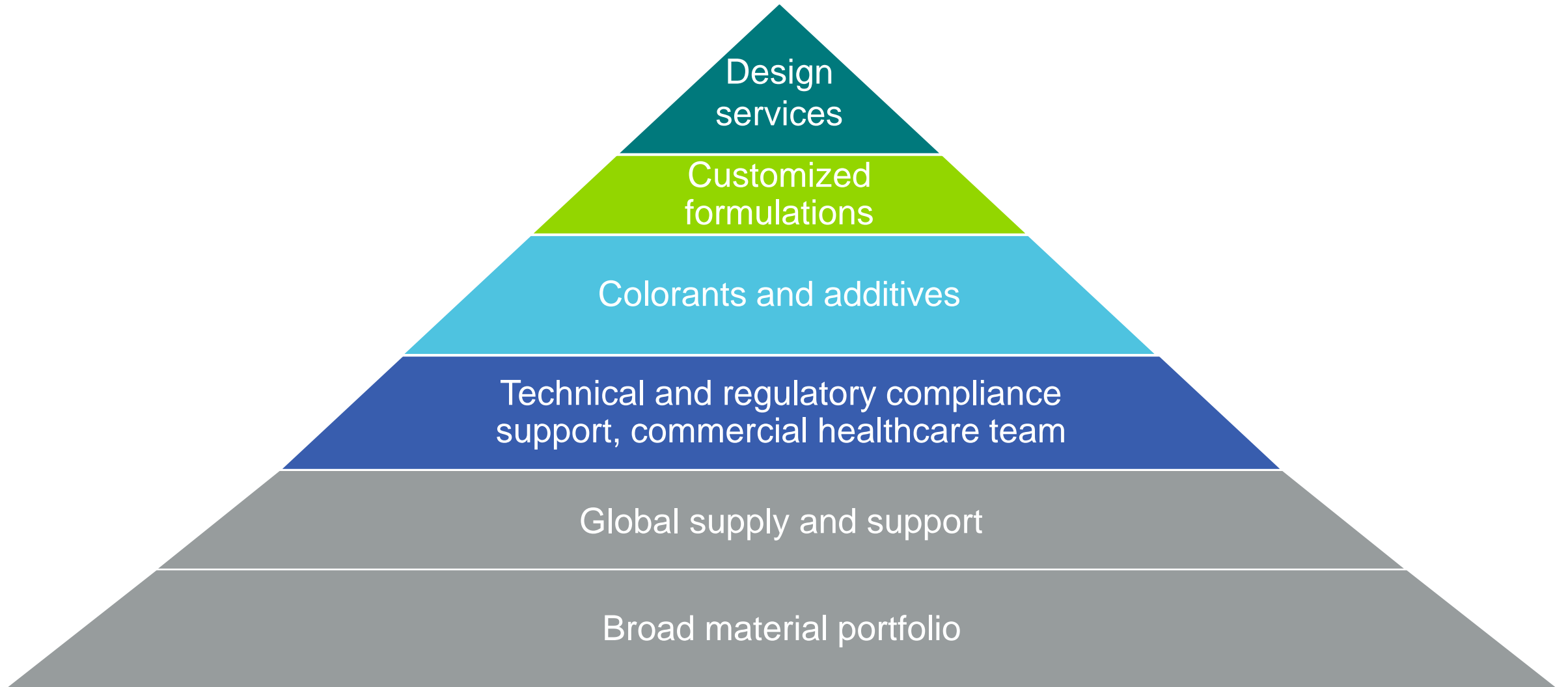
125
facilities in
35 countries

OUR MISSION

ENABLE OUR CUSTOMERS' INNOVATION AND SUSTAINABILITY
GOALS THROUGH WORLD CLASS PRODUCTS AND SERVICES

BREADTH OF SERVICES

TOP TO BOTTOM CAPABILITIES



THANK YOU FOR YOUR TIME!

Contact: Eric Rohr
Eric.Rohr@Avient.com