



Behind the scenes of optical filter production: precision coating processes create the functional layers that define filter performance

From concept to production

Early optical specification collaboration in medical devices – using optical filters as a case study

Nicole Zombotti and Anna Hetzelt

Medical technology sits at the intersection of innovation, precision, and responsibility. Every component must not only perform in an initial prototype, but also remain consistent as the product moves through verification, regulatory review, and serial production. Achieving that consistency requires the medical-device developer and component manufacturer to define requirements together, early enough to influence both the system design and the production strategy.

Optical filters illustrate why early collaboration matters. Their required performance depends on the source, detector, beam geometry, environment, and clinical purpose

of the complete system. A prototype demonstrates what one filter achieved; the specification defines what every production filter must achieve. If it does not capture the performance on which the system depends, a conforming filter can still produce different system results.

Planning for regulatory and change-control requirements

The FDA's Quality Management System Regulation incorporates ISO 13485:2016, while Europe's MDR and IVDR similarly emphasize risk management, documentation, traceability, and lifecycle control. Although an optical supplier does not obtain approval for the finished device, its processes, records, and

notifications can affect the device manufacturer's compliance.

When an optical material, coating process, manufacturing platform, facility, or inspection method changes, the device manufacturer must assess whether the change could affect safety, effectiveness, or validated performance. Depending on the risk and the result of that assessment, additional verification, validation, documentation, or regulatory action may be required. Post-qualification discovery that a prototype process is poorly suited for production can therefore create substantial cost and delay.

This is why supplier selection matters early. An established supplier should formally review process changes, maintain traceability,

and notify customers according to agreed change-control requirements. Not every company capable of producing a technically acceptable filter has sufficiently robust systems to manage change control consistently.

Optical filters as a case study

A common example is the transition from ion-beam sputtering (IBS) to magnetron sputtering. Both technologies can produce dense, durable, high-performance optical filters, but their equipment and production economics differ. IBS chambers are generally smaller, making them attractive for development quantities. Producing three to ten prototype filters in a smaller chamber can cost less per coating run and waste less unused substrate area, even though the resulting price per part may be higher than at production volume.

Magnetron sputtering becomes more favorable as demand increases because a larger chamber can accommodate more substrate area in a single coating run. Coating only a few prototypes in a production-scale chamber remains inefficient because most coating-run costs are incurred whether it contains two wafers or twelve. Partial loading reduces wasted glass, but it has limited effect on the total run cost.

Ion-beam sputtering may therefore suit low-quantity prototypes, while magnetron is intended for serial production. If a system qualified with IBS filters transfers later, the change must be controlled and evaluated. Once the expected production volume is understood, the parties should agree on the intended production process and determine when production-representative filters must enter the verification process.

The specification defines production performance

Transferring a coating between platforms is not simply a matter of running the same recipe in a larger chamber. Differences in coating design, deposited material properties, chamber geometry, substrate motion, and process control can produce filters that are not identical. An IBS filter and a magnetron filter may both satisfy the same requirements for physical thickness, transmission, blocking, and flatness while differing in spectral details or visual appearance.

An IBS prototype may also substantially exceed the written requirements. A drawing might require greater than 90 % transmission and OD5 blocking, while the IBS-produced prototype provides 96 % transmission and blocking approaching OD6. If the medical

system is developed around that additional margin, a magnetron filter that meets – but does not exceed – the original requirements may provide less signal or more background. The production filter is conforming; the specification simply did not capture all of the performance characteristics on which the system came to depend.

The filters may even appear to be different colors because their spectra differ outside the controlled regions. This does not necessarily indicate a defect, but it can confuse incoming inspection or assembly personnel and interrupt production.

The goal is not to reproduce every incidental characteristic of an early prototype. It is to determine which characteristics are essential to the medical system, establish appropriate margin, and translate them into measurable requirements that the supplier can manufacture and inspect consistently.

How filter specifications affect medical-device outcomes

Center wavelength, bandwidth, transmission, and blocking are starting points, but they do not completely describe filter performance. Requirements depend on the filter's position, what light must pass or be rejected, and the consequence of unwanted light reach-



Quantum Sensing at Cryogenic Temperatures.

attoNVM

cryogenic NV microscope

- μT sensitivity & nm-scale resolution combined
- ultimate stability over long measurement cycles
- NV diamond tips with integrated rf antenna



Join our webinar!

attocube
WITTENSTEIN Group



At the heart of medical innovation, optics enable precision, performance, and new possibilities in medical devices.

ing the sample, detector, camera, patient, or observer.

Fluorescence diagnostics

In fluorescence microscopes, PCR systems, flow cytometers, and other diagnostic instruments, excitation and emission filters must be evaluated as a pair. Their edges and tolerances must keep intense excitation light from reaching the detector. Insufficient blocking can raise background, create crosstalk, or obscure a low-level signal, potentially contributing to a false-positive, false-negative, or other incorrect classification.

Autofluorescence is the natural emission of light by biological tissue, cells, substrates, adhesives, or other materials after optical excitation, without an intentionally added fluorescent label. It is often overlooked when filters are specified only around the fluorophore's peak wavelengths. If the filter passbands also collect strong autofluorescence, the increased background can reduce signal-to-noise ratio and detection sensitivity even when the intended fluorescence is transmitted efficiently.

Fluorescence-guided surgery

In fluorescence-guided surgery, filters help visualize markers used to distinguish tissue, assess perfusion, or identify structures in real time. The system must transmit fluorescence while rejecting stronger excitation light, tissue autofluorescence, and ambient background. Leakage can reduce contrast or saturate the camera; uneven performance can vary brightness across the field. The result could be incomplete or misleading guidance when identifying tissue boundaries or evaluating perfusion.

Medical lasers

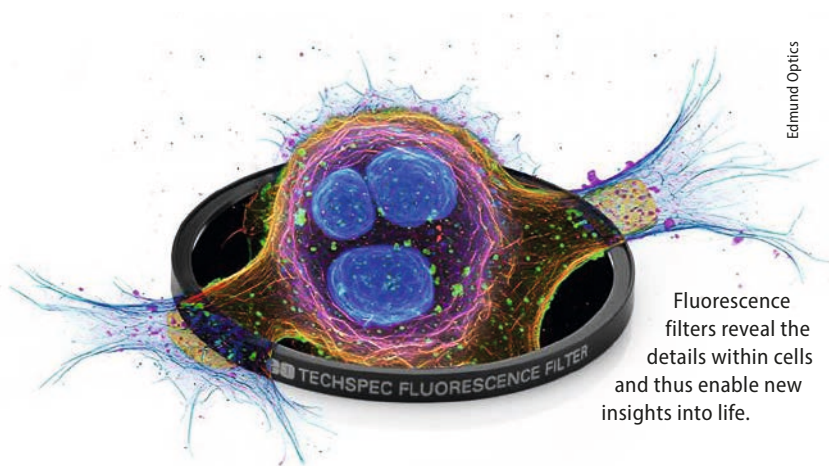
In medical-laser systems, filters may select the intended wavelength, reject unwanted emission, attenuate

power, or route wavelengths along separate paths. Requirements may include blocking range, transmission or reflection at the actual use angle, polarization sensitivity, power handling, and laser-induced damage threshold. Too little delivered energy may result in an ineffective or incomplete treatment; too much energy, an unintended wavelength, or a damaged filter may increase the risk of excessive heating or injury to tissue. For this reason, filter performance must be specified in the context of the laser's intended clinical function, rather than evaluated as an isolated component.

Specifications must include operating and measurement conditions

A spectral requirement is incomplete if it does not define the conditions under which it must be met. Using an interference filter at an angle other than its nominal design angle shifts its spectral response. A converging or diverging beam contains a range of incidence angles, or cone half-angle, that can broaden an edge or passband. Polarization can introduce further differences, particularly at larger angles.

Orientation also matters. Many interference filters are not optically identical on side 1 and side 2 because the functional multilayer coating and the opposite-side



Fluorescence filters reveal the details within cells and thus enable new insights into life.

coating may serve different purposes. Installing the filter backward can increase back-reflections, stray light, or ghost images and may change how light interacts with the coating and substrate. The drawing, housing, and assembly instructions should identify the required orientation using a durable, unambiguous convention.

Clear aperture and spatial uniformity must also be considered. A measurement at the center of a witness sample may not represent performance over the usable area of every finished filter. The specification and inspection plan should define the relevant aperture, measurement locations, spectral resolution, and whether compliance is based on average, minimum, or absolute performance.

Depending on the application, a production-ready filter specification may include:

- Passband wavelength range, edge locations, tolerances, and minimum transmission,
- blocking level and the complete wavelength range over which it applies,
- pinhole inspection requirements, where criteria should define allowable defect size, quantity, location, illumination conditions, and detection method,
- angle of incidence, cone half-angle, and polarization conditions,
- clear aperture and spectral uniformity across the usable area,
- filter orientation, side identification, and controls for back-reflections or ghost images,
- physical thickness, wedge, flatness, or transmitted wavefront, as relevant to the optical path,
- surface quality, cosmetic requirements, and applicable ISO 10110 drawing indications,
- operating temperature, humidity, cleaning, and environmental durability,
- optical power density and laser-induced damage threshold, where applicable,
- measurement equipment, spectral resolution, sampling plan, and acceptance calculation,
- lot traceability, approved production platform, and customer change-notification requirements.

Collaboration turns system needs into controlled production

Early specification work is most effective when the medical-device developer shares the system-level information that drives optical performance. For the filter examples discussed here, this may include the source spectrum, detector sen-



**Physik
Journal**

Newsletter

**Was
Physiker:innen
morgen bewegt –
heute in Ihrem
Postfach.**

Forschung, Karriere,
Innovationen und DPG-News
– kompakt im Physik Journal
Newsletter.

Jetzt kostenfrei
abonnieren



Adobe Stock/ Lin 800



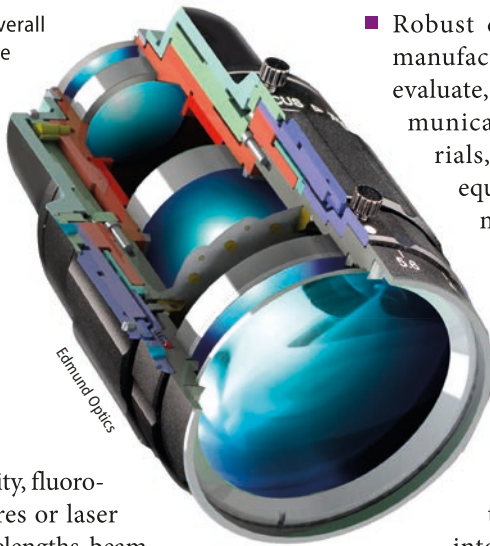
Ready for Next-Level PIC Testing?

Modular Hardware and
Software for Electro-Optical
Characterization.

SmarAct

SmarAct GmbH
+49 441 8008790
info@smaract.com
www.smaract.com

A device's overall optical performance depends on the precise integration and interaction of multiple optical elements within the complete system.



sitivity, fluorophores or laser wavelengths, beam geometry, environmental conditions, assembly constraints, and performance targets. A collaborative optical manufacturer can then translate those needs into requirements that are technically meaningful, manufacturable, and measurable.

This principle extends beyond filters. The combined tolerances of lenses, prisms, mirrors, windows, coatings, and other components ultimately determine system performance. For optical subsystems and complex assemblies, early collaboration allows optical, mechanical, alignment, manufacturing, and inspection requirements to be considered together against the device's imaging, detection, or treatment requirements.

When selecting an optical manufacturing partner for a medical-device program, important considerations include:

- An ISO 13485-certified quality-management system: Look for established processes supporting documentation, traceability, risk-based controls, nonconforming product, and corrective action.

- Robust change control: The manufacturer should identify, evaluate, document, and communicate changes to materials, platforms, facilities, equipment, or inspection methods. Customer-notification requirements should be established before production.

- Collaborative specification development: The manufacturer should translate system needs into measurable component and assembly requirements so conforming optics support consistent production performance.

- Transparent communication about capability and capacity: The manufacturer should demonstrate the technology, equipment, capacity, and quality controls needed for both successful prototypes and repeatable, on-time volume production. Potential platform transfers, limitations, and qualification requirements should be addressed before design freeze.

A filter that passes its drawing – or an assembly whose components pass inspection – may still be insufficient if the requirements do not reflect the complete system. The right optical partner helps develop those requirements, designs, and manufactures with the final application in mind, controls production, and communicates changes. The specification then becomes the shared technical link between a successful prototype and a reliable medical product.

References

- [1] U.S. Food and Drug Administration. Quality Management System Regulation (QMSR). Effective February 2, 2026. <https://tinyurl.com/fda-qsmr>
- [2] U.S. Food and Drug Administration. Deciding When to Submit a 510(k) for a Change to an Existing Device: Guidance for Industry and Food and Drug Administration Staff. 2017. <https://tinyurl.com/fda-download>
- [3] Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices
- [4] Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices
- [5] ISO 13485:2016. Medical devices – Quality management systems – Requirements for regulatory purposes. <https://www.iso.org/standard/59752.html>
- [6] ISO 10110-1:2019. Optics and photonics – Preparation of drawings for optical elements and systems—Part 1. <https://www.iso.org/standard/57574.html>
- [7] ISO 14997:2017. Optics and photonics – Test methods for surface imperfections of optical elements. International Organization for Standardization. <https://www.iso.org/standard/63464.html>
- [8] A. C. Croce and G. Bottiroli, *Eur. J. Histochem.* **58**, 320, 2014
- [9] K. E. Tipirneni et al., *Ann Surg.* **266**, 36, 2017
- [10] D. Obeid, Edmund Optics, <https://tinyurl.com/eo-filter>

Authors

Nicole Zombotti

Business Development Manager
Optical Filters

Anna Hetzelt

Technical Content Specialist

Edmund Optics Mainz
Isaac-Fulda-Allee 5
55124 Mainz
Germany
Website: www.edmundoptics.de