



## **The Role of Industry Representatives in the Endoscopy Unit**

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### Introduction

The modern endoscopy unit is a busy workplace environment. With the patient as the main focus of activity, providers and staff engage in delivering endoscopic services on a daily basis, ranging from basic general endoscopic procedures in an Ambulatory Surgery Center (ASC) to the most advanced complex interventions performed at tertiary academic medical centers.

Our ability to acquire, optimally utilize and maintain endoscopic accessories, devices, and equipment allows provision of high quality endoscopic procedures. Furthermore, the findings of endoscopy often dictate subsequent pharmacotherapy. Industry representatives, acting on behalf of the device, pharmaceutical, and equipment manufacturers, play an important role in helping us achieve this goal. This document was prepared because there is no formal guidance to define the roles and responsibilities of industry representatives in the endoscopy unit.

This document will:

- Describe the role of the industry representative in an endoscopy unit
- Suggest how industry representatives may best engage in that role
- Recommend how to achieve an optimal partnership between industry representatives and the endoscopy unit in the best interest of the patient
- Define the educational and training needs for effective interaction by industry representatives with providers and staff in the endoscopy unit

### Hospital credentialing, HIPAA certification, and general code of conduct

A variety of vendor credentialing services are available that health care institutions may use to verify representative credentials and confirm up-to-date compliance with vaccinations and tuberculosis testing, with the intent of increasing safety and reducing liability. Representatives should be in compliance with all credentialing and HIPAA requirements before visiting the endoscopy unit. At the time of a visit they should wear prominent identification that clarifies their role and allows them access to patient care areas, in accordance with the local institutional policies. When present during a procedure, the role of the representative is that of an observer and advisor related to products and a source of information and not as an active participant. Patient consent to have representatives present during a procedure is recommended and should comply with

local institutional policy. Representatives should not take videos or photographs during procedures.

### Types of industry representatives

The types of industry representatives encountered in an endoscopy unit may be diverse and are listed in Table 1. The most common are the device or accessory sales representatives (referred to here as product representative). Endoscope or other major equipment sales representatives, pharmaceutical representatives, product specialists, market development managers, scientific liaisons, and members of senior corporate leadership are other types of industry representatives that may interface with endoscopy unit personnel from time to time. Each has a specific job description and role to play. This document will focus on the product and pharmaceutical sales and marketing representatives, which are the most common types of industry representatives encountered in an endoscopy unit.

### What are the roles of an industry representative?

The most common role of the representative is to introduce a specific product or technology and to facilitate its purchase by the endoscopy unit or healthcare facility, and to provide after-sales service and support. Additional roles are listed in Table 2. Some of these roles vary depending on the scope and nature of a particular endoscopy unit's activities as well as the different needs that arise from time to time. In some units, representatives may also support research projects. It is important to keep the research support role completely separate from that related to product service, education, and support.

### Device and accessory sales and service

A variety of accessories and devices are used on a daily basis in an endoscopy unit. The representative commonly facilitates introduction and purchase of these products by working with the unit leadership and the purchasing department. These devices are typically cleared by the U.S. Food and Drug Administration (FDA) and commercially available items that include products ranging from standard accessories (eg, biopsy forceps, polypectomy snares, stents, etc.) to more complex devices (eg, cholangioscopy equipment, enteral stents, etc.).

Several companies may manufacture similar items, resulting in a competitive environment for the representative. To be successful, the representative should have comprehensive knowledge of the product, including its proper use in appropriate clinical settings. Representatives with the proper training and understanding of device function are more likely to confidently instruct and educate the unit staff on safe and appropriate use of the product, earning greater respect for their important and integral role. At all times, the device/accessory representative should conduct themselves in compliance with the AdvaMed Code of Ethics on Interactions with Health Care Professionals.<sup>1</sup>

In addition, when a device or equipment malfunction arises, the representative has a duty and obligation to be available and receptive to the customer's needs and to bring a satisfactory resolution to the problem at hand. This is a critical role, especially in smaller endoscopy units where fewer alternatives (or "back-ups") exist in the event of device malfunction. These units may depend highly on rapid resolution of the problem in order to maintain daily activities.

### Major equipment sales and service

Industry representatives are also responsible for sales and service of endoscopes (which often represents the largest capital investment in the unit) and other, specialized types of capital equipment a unit may acquire (eg, endoscopic ultrasound equipment, cholangioscopy, and ablation equipment, etc.). These major investments require in-depth knowledge on part of the representative, not only to facilitate sales but also to address any ongoing issues that may arise with either the equipment or the contract. In many cases, companies assign "product-specialists" to help establish and/or service specific types of equipment. These specialized representatives have more in-depth product specific knowledge, training and expertise and serve as a resource for physicians and unit staff. As with device and accessory representatives, the equipment representative must conduct themselves in compliance with the AdvaMed Code of Ethics on Interactions with Health Care Professionals.<sup>1</sup>

### Pharmaceutical representatives

Endoscopy is used to diagnose and treat a variety of GI disorders. Many of these conditions require pharmacotherapy either for the specific GI condition or for the related or underlying disease process. For example, specific GI conditions that are diagnosed with endoscopy include acid peptic disorders (esophagitis, peptic ulcer disease) and inflammatory bowel disease (ulcerative colitis, Crohn's disease). Pharmacologic treatments are often prescribed as a result of the findings on endoscopic evaluation. Patients with underlying medical conditions such as liver disease, pancreatic or biliary conditions, and motility disorders also undergo endoscopic evaluation. Thus these patients may require medications for their hepatitis, pancreatic insufficiency, or motility issues to name a few. The pharmaceutical representative needs to have up-to-date information regarding their product as well as the GI pathophysiology of the condition and the role of endoscopy in its diagnosis or management. The ultimate role of the pharmaceutical representative is to provide the clinicians and staff with information and resources for use of their medical product to treat patients optimally. At all times the pharmaceutical representatives should conduct themselves in compliance with the PhRMA Code on Interactions with Healthcare Professionals.<sup>2</sup>

### Introduction to New Technology

Not infrequently, it is the industry representative who introduces a new device or accessory to the physicians and staff in an endoscopy unit. In many cases, new technology helps simplify function, increase efficiency, enhance performance and/or reduce risk to patients and providers, thus directly impacting patient care and the quality

of the services provided. Introduction to new products and technology is thus a significant service performed by industry representatives and is an important partnership that leads to growth and evolution of endoscopy units over time.

Exciting as new technology is, representatives need to be cognizant of a few caveats. First, there may be an associated incremental cost burden and justification for increased expenditures will be required. Second, representatives should be clear whether a new product is FDA-cleared and commercially available, or is currently “investigational” and commercially unavailable to be used only in defined scientific protocols. Finally, most institutions have a defined approval process in place to facilitate incorporation of new technology (the “Value Analysis” process); representatives need to be aware of this process and proceed accordingly, refraining from ad-hoc sale and use prior to such approval.

In the case of FDA-cleared “limited launch” products (typically made available to expert centers before full commercial launch) the representative will typically seek formal, written feedback related to device performance from the endoscopist/staff.

#### Physician and staff “in-service”

From time to time, physicians or staff in an endoscopy unit might request and benefit from hands-on product demonstrations, the so called “in-service.” This is not only applicable to new devices, but also is useful for periodic updates on equipment that is infrequently used (eg, mechanical lithotripter) or complex devices (eg, electrosurgical generators). Industry representatives typically facilitate this important exercise, occasionally using animal explant models. Other exercises may focus on specific initiatives of particular importance to a unit, such as appropriate endoscope re-processing methods that directly impact infection control and patient safety. These programs contribute to ongoing staff education and can also serve as quality improvement initiatives, positively impacting patient care.

#### Intra-procedural observation and support

Frequently, industry representatives are present during endoscopic procedures. This may occur at the physician’s request, as a result of their own initiative, or as part of representative training. It is important to clarify the role of the industry representative in this setting. First, the representative should be HIPAA certified and allowed into the procedure only upon the consent of the patient. Second, the representative should not under any circumstance participate in the procedure or any patient care activity. The role of the representative is strictly observational or limited to providing technical advice or information related to the product being used. This information should be verbally communicated to the endoscopist or the assistant, but at no point should the representative actively participate in the procedure. In other words, the representative cannot assume the role of the endoscopy nurse or technician at any time during the procedure. This is a key principle that needs to be emphasized given the frequency with which representatives are present during procedures, the potential for “blurring of lines” vis-à-vis individual responsibility (especially during difficult and challenging procedures)

and the medico-legal implications related to active participation by a non-clinical observer.

### Liaison role and relationship building

Every industry representative has an opportunity to serve a liaison role between the endoscopy unit and the manufacturer. Facilitation of two-way communication, whether it is related to a new device or conflict resolution, is one of the most important functions that representatives serve. They are the “eyes and ears” of the manufacturer in the field and can impact the relationship through their conduct and professionalism. Customizing sales to the needs of the unit, providing timely after-sales service, and simply “being available” when the need arises generates respect for the representative and enhances the reputation of the company they represent. Representatives may help initiate contact and dialog with appropriate personnel within the company to facilitate projects related to device development and innovation in endoscopy, or help support CME events and hands-on workshops. The potential for this role should not be discounted as it can result in enduring partnerships based on mutual trust, respect and the singular focus of providing the best patient care.

### Educational requirements and curriculum

Device and pharmaceutical representatives must have extensive knowledge and training regarding both their specific product(s) and, more generally, gastroenterology, hepatology, and endoscopy. These latter areas are common to all representatives and form the basis for a common curriculum. The objectives of this training include understanding basic GI anatomy and physiology, common GI diseases and their endoscopic findings, and the basics of endoscopy and endoscopic therapy. As needed, this education should be supplemented with specific educational topics such as inflammatory bowel disease, gastroesophageal disease, pancreaticobiliary disease, etc. Hands-on training with simulators is especially useful. Certification of successful training is recommended. The ASGE has recently introduced a dedicated industry professional training program ([ARIA: ASGE Recognized Industry Representative](#)) that has didactic and hands-on components, designed to help train representatives. Table 3 outlines a suggested curriculum.

### Summary and final recommendations

Industry representatives serve an important and multifaceted role in the endoscopy unit. As described above, there are many elements that are necessary for a successful and meaningful relationship with the endoscopy unit, ultimately aimed at enhancing patient care and achieving the highest levels of professional satisfaction for all stakeholders.

### Key recommendations are summarized below:

- Appropriate training and education for representatives is essential.

- Corporate educational and training curriculum, preceptorships, ARIA program, etc.
- Representatives should be formally credentialed with the hospital(s)/ASC facility, including HIPAA and any other site-specific requirements.
- Representatives must comply with AdvaMed and PhRMA codes and local policies on interactions with healthcare professionals.<sup>1,2</sup>
- Patient consent is recommended for intra-procedural observation. Representatives should not take videos or photographs during procedures.
- During procedures, representatives are expected to provide “guidance only” vis à vis function and technical aspects pertinent to their device or equipment.
- Representatives may not participate in a “hands-on” fashion during endoscopic procedures.
- Representatives should not advise on clinical decisions or equipment selection for specific procedures or patients.
- When in place, the value analysis process for device and pharmaceutical acquisition needs to be respected and followed by representatives. Not doing so may have financial and medico-legal implications.
- When introducing new technology to the endoscopy unit, the distinction between FDA-cleared and non-cleared devices and accessories needs to be made clear explicitly.
- Formal initial and periodic “in-service” sessions for unit staff and providers are recommended to gain and maintain familiarity with medications and new equipment, especially for complex devices or accessories.
- Representatives should request a formal, written physician evaluation/assessment for “limited launch” and novel products to provide valuable feedback from the field.
- Knowledge of complications or adverse events related to pharmaceuticals, devices and equipment should be shared openly by the representative with physicians/staff.
- Negative commentary regarding a competing device/manufacture should be avoided by all professionals.
- Relationship building, mutual respect, and ethical conduct will lead to a strong and enduring partnership with the endoscopy unit staff and providers.

As discussed, the role of an industry representative is more significant and impactful than just providing sales and service of endoscopy related equipment and medications. They serve critical roles in facilitating communication between institutions and manufacturers, assist with contract negotiations and information delivery, help with technology and new treatment acquisition, and provide opportunities for hands-on skill and knowledge acquisition for staff.

In many instances, deep, enduring personal and professional relationships are formed between the industry representatives and the endoscopy unit personnel that ultimately enhance the overall quality of the unit and the care of the individual patient.

**TABLE 1. Different types of industry representatives**

1. Device and accessory sales representative
2. Endoscope and equipment sales representative
3. Pharmaceutical representatives
4. Product support specialists
5. Market development managers
6. Scientific liaisons
7. Senior leadership team members
8. Other (project specific) representatives

**TABLE 2. Various roles of industry representatives**

1. Device and accessory sales and service
2. Endoscope and major equipment sales and service
3. Introduction and incorporation of new technology
4. Providing equipment related “in-service” for staff
5. Delivering provider and staff education for use of pharmaceuticals
6. Intra-procedural device related support
7. Liaison role



**TABLE 3. Curriculum for industry representatives**

***Gastrointestinal Tract in Health: Basic Anatomy and Physiology***

- Foregut: Esophagus/Stomach
- Midgut: Small Bowel
- Hindgut: Colon/Rectum
- Hepatopancreaticobiliary

***Tools of the Gastroenterologist***

- Introduction to GI Endoscopy —EGD, Colonoscopy, ERCP, EUS, Enteroscopy
- Other Tests Used by Gastroenterologists—pH testing, Manometry, Radiology, Emerging Technologies

***Gastrointestinal Tract in Disease: Overview of Major GI Disorders***

- Foregut: Esophagus and Stomach
- Midgut: Small Bowel
- Hepatopancreaticobiliary Disease
- Colon/Rectum

***Hands-on Simulator Training***

- Basic Scope Handling/Foreign Body Removal
- APC/Bicap/Thermal Therapies
- Injections/Clip
- Bands/Polyps

***Additional Topics:***

**Inflammatory Bowel Disease**

- a. Overview of IBD and extraintestinal manifestations
- b. IBD-diagnosis
- c. Medical therapies for IBD
- d. Surgical management of IBD

**Gastroesophageal Reflux Disease**

- a. Pathophysiology and Epidemiology of GERD
- b. GERD: Diagnosis
- c. GERD: Medical, endoscopic and surgical management
- d. Barrett's esophagus and Esophageal Cancer: Epidemiology, diagnosis and management

**Pancreaticobiliary Endoscopy 101**

- a. The Bile Duct: Stones, strictures, tumors and other obstructing lesions
- b. Understanding acute and chronic pancreatitis
- c. Understanding ERCP and EUS: Tools of the Trade

**Hepatitis & Liver Disease**

**Practice Management 101**

**New Technology**

**Communication Tips and Strategies and Code of Conduct**

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