While the primary goal of the clinical development team is to obtain product approval, companies must have a broader vision that supports the complete product lifecycle. Experts in regulatory advertising and promotion (A&P) have a detailed knowledge of the US Food and Drug Administration (FDA) requirements for product promotion. Beyond supporting the promotional review process, the unique skill set of regulatory A&P should be applied to other critical activities, including clinical study protocols and target product profiles (TPP).

Introduction
A cursory search for regulatory A&P job postings will often include core responsibilities such as, “serves as an internal expert on FDA regulations, guidance, and enforcement trends governing the promotion of prescription drug and biologic products” and “conducts reviews of proposed commercial communications to ensure consistency with product labeling and compliances with the FDA regulations and applicable laws.” These are critical aspects of the job because healthcare providers, patients, and patient advocacy groups rely on
the healthcare industry as a source for truthful, accurate, and balanced product information, which aligns to the mission of the Office of Prescription Drug Promotion.1

Regulatory A&P professionals understand and interpret complex issues around regulatory requirements and promotional strategy. With this skill set in mind, it is important to consider other opportunities to provide value, particularly in the years preceding product approval, for example, whether earlier involvement by these regulatory professionals could help influence the commercial trajectory of a product. That is an important consideration, because earlier involvement would contribute to commercial success and result in healthcare providers and patients having timely access to relevant product information.

The role of the regulatory A&P professional
A regulatory A&P professional is often a member of an interdisciplinary promotional review committee (PRC) comprised of medical, legal, and commercial representatives. The committee is tasked with reviewing a range of product promotional materials, including visual aids, patient brochures, websites, social media, and television advertisements. The committee may also review sales training, disease communications, and other internal communications. That is no easy feat – the advertising and promotion space is often nuanced and complex and requires team members to stay current with the evolving competitive landscape.

The primary regulatory A&P responsibility is to thoroughly review and assess proposed promotional communications to evaluate their completeness, accuracy, and compliance with regulatory requirements, however, much work is done outside of PRC meetings. Reviewers can spend many hours evaluating promotional materials to ensure consistency with the product labeling and researching previous FDA insights, including FDA enforcement letters and voluntary company advisory comment submissions. They may also consult subject matter experts in clinical, regulatory strategy, and biostatistics (among other functions) when complex challenges warranting unique insights arise. This background research and diligent review allows regulatory A&P professionals to educate their PRC colleagues and contribute to commercial strategies. This helps support the company’s overall goals by producing compliant communications and offering creative solutions to address potential FDA concerns, including risk mitigation approaches.

While these responsibilities are important and enable healthcare providers and patients to make appropriate and well-informed decisions regarding healthcare, there is further value regulatory A&P can bring to the organization.

Value beyond the PRC
The skill set of a regulatory A&P professional offers a unique vantage point as a bridge between research and development (R&D) and commercial functions.
Target product profiles
Aligning on key commercial strategies and core messaging early in the clinical development process is critical and involves close cross-functional collaboration. The development of a TPP can be an invaluable tool in identifying desired product attributes, including critical components of the product label, such as indication, dosing and administration, warnings and precautions). The FDA issued a draft TPP guidance in 2007, which was used to facilitate discussion between the manufacturer and the FDA. Although the agency withdrew the draft guidance in 2019, companies may still find elements of it helpful in building the roadmap from R&D to commercialization. The TPP can also inform future evidence generation activities, such as clinical studies and registry participation, as well as market access implications.

The TPP is developed with the end goals in mind, and the process of developing the profile can help align goals and efforts among the respective stakeholders, particularly in regard to desired promotional claims. It is necessary for a regulatory A&P professional to understand the commercial landscape and promotional strategy to be able to advise the PRC. Product claims must be grounded in good science if they are to be truthful and non-misleading. Data and analyses should be scientifically appropriate and statistically sound. To that point, the opportunity to evaluate the methodology of clinical study design and the clinical endpoints being assessed allows a regulatory A&P to establish whether the desired promotional claims can be supported or if the protocol needs to be changed. (In some cases, particularly with phase 1 or 2 clinical trials, regulatory A&P might be asked to provide input on study design.) This proactive, early involvement by regulatory A&P can influence the likelihood of having an impactful product label and subsequent inclusion of certain data in promotional materials.

Product label strategy
It is also important to consider the internal strategy for product labeling. The labeling working group, of which a regulatory A&P professional often is a member, should evaluate the draft labeling for inclusion of key concepts that would maximize commercial impact while ensuring appropriate and clinically meaningful information is available for healthcare providers and patients. Understanding what and when to negotiate with the FDA during labeling negotiations should be evaluated as part of the strategy discussion among the labeling working group. For example, the company might consider whether the guidance for consistency with FDA-required labeling is applicable, particularly if certain information is not included in the final approved label.

These critical activities should not be overlooked – the product’s success can be attributed directly to the strength of the product label, which serves as the primary source for claims in promotional materials.
Building strong relationships
Successful and compliant promotional campaigns begin with strong, cross-functional partnerships. The regulatory A&P professional is often viewed as a leader of the PRC, trying to achieve consensus when possible. To be an effective and efficient team, the committee members have to trust each other and appreciate the diversity of expertise. Disagreements are a natural part of the collaborative process and can foster creative thinking.

The innate leadership of regulatory A&P professionals can be applied to other complex situations, including TPP development. Team members rely on their regulatory A&P colleagues to critically evaluate commercial proposals in real-time, due in part because they can easily glean insights from previous knowledge and experiences (e.g., FDA enforcement actions and advisory comments) and apply the information to the situation at hand. As experts in all aspects of A&P, regulatory A&P professionals have a unique opportunity to build trust as an educational leader by providing rational, evidence-based regulatory information to support potential solutions.

Summary
The core responsibility of regulatory A&P is to protect the company by mitigating regulatory risk and providing expert advice on how best to navigate regulatory A&P ambiguity. The regulatory A&P professional is an important bridge between research and development of a product to its commercialization. As the role continues to expand, the regulatory A&P professional can help influence commercial success by ensuring clinical data supports desired promotional messages. To optimize success, earlier involvement in the clinical development program, with a focus on supporting TPP efforts, is needed. In addition, regulatory A&P insights on draft labeling and subsequent labeling negotiations with health authorities can inform strategies for appropriate execution in promotion throughout the product lifecycle.

Although the activities beyond the day-to-day scope can be time and resource intensive, the benefits far outweigh any downside. If there is an opportunity to positively influence the commercial trajectory and better support the needs of healthcare providers and patients, regulatory A&P professionals must take on that challenge.

Abbreviations
A&P, advertising and promotion; FDA, [US]Food and Drug Administration; PRC, promotional review committee; R&D, research and development; TPP, target product profile.

About the author
Kristen Heinlein, PharmD, is a vice president, US, of regulatory advertising and promotion at Takeda, with more than 16 years of pharmaceutical industry experience. Heinlein obtained a doctor of pharmacy degree from the University of the Sciences in Philadelphia. She can be contacted at kristen.heinlein@takeda.com
Citation Heinlein K. Regulatory advertising & promotion: Bringing value beyond the day-to-day. Regulatory Focus. Published online 22 December 2021. https://www.raps.org/news-and-articles/news-articles/2021/12/regulatory-advertising-promotion-bringing-value-be

References
All references were accessed on 13 December 2021.


5. Food and Drug Administration. Medical product communications that are consistent with the FDA-required labeling questions and answers [guidance for industry, June 2018]. https://www.fda.gov/guidance/media/133619/download. Last updated 30 September 2021.