USNC IEC Young Professionals Competition

Candidate Essay – Ashleigh McNaboe

The medical device field is just one of the many sectors of the standards conformance industry. It has experienced substantial transformation since the creation of the IEC 60601 series of standards 47 years ago. Three full editions, one new edition on the horizon, and multiple additional collateral and particular standards later, this series has highlighted just how much the standards industry must evolve to keep up with innovative and ever-changing technological advancements. Like other industries in the standardization and conformity assessment community, the medical device industry had to adapt over time, while also considering patient safety, user safety, and new clinical and medicinal best practices. As industries prepare for the next 47 years of technological innovation, leaders should focus on proactively writing foreseen technological trends into standards, ensuring accessibility and awareness of standards across the global market, and attracting and training the standards experts of tomorrow.

With emerging markets and advancements in enabling technologies, industries will pivot to meet the needs of these changing practices. For medical devices, new environments have already begun to emerge in the home healthcare and telehealth spaces, in which patients will be an increasingly imperative stakeholder in standards development, along with clinicians, regulators, academics, and industry representatives. And with the healthcare industry pivoting to prevention tactics in addition to the clinical care of patients, technologies will emerge to meet the market demand and further the benefit of patient health. The future of standards conformity should include the forward thinking of what innovations are to come, and the new safety concerns and hazardous situations that come with them. As one edition may be seen as the consensus for over a decade, shaping the path for new technologies while not stifling innovation will be a difficult yet exciting task.

The standards community should also consider the accessibility and awareness of standards existence across the global market. The intent of standards is for all applicable technologies, across a wide range of major manufacturers to start ups and accelerators, to meet consensus best practices and requirements. The industry should ensure that these standards are financially accessible, globally harmonized, and communicated to applicable stakeholders for awareness of new trends, standards, editions, and amendments. Standards should not be cost prohibitive but accessible and intuitive as possible with minimal deviations required across the globe. Harmonization and consensus worldwide will lead to streamlined safety and more access of emerging technologies across the world for the user's benefit.

Lastly, the community should contemplate how they can energize young professionals to participate and retain experts within the field. The community should consider starting an education pathway, familiarizing students on the role standards play in our everyday lives. They should also continue to mentor young professionals and provide additional measures to succession plan within key roles in the industry. Standards conformity drives the industry from the ground up, containing base requirements to sell many products around the world, and it is

imperative to have resources that are retained within the field to help guide the industry into a successful future.

It is an exciting time to be part of the standards industry, as innovation is on the rise and the standards conformity realm gives individuals a unique perspective to be a part of something bigger than their employer or country to ensure safety, improve efficacy, and shape tomorrow's technology all around the world. We should ensure that we continue to proactively think beyond the current technologies of today, expand global understanding and access, and attract, train, and retain our talented pool of experts, striving to shape standards best practices and create safe and innovative products.