

ISCT ESP Mentoring Experience for Quality Assurance and Regulatory Affairs: Both Sides of the Coin

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Background:

The ISCT ESP Mentoring Program was implemented to identify seasoned leaders in various aspects of Cell and Gene Therapy (CGT) and connect them to self-identified Early Stage Professionals (ESP) with interests in the same area. The intent is to provide professional and leadership development support, but technical mentoring is outside the scope of this program. Since its inception in 2017, the Mentoring Program has connected volunteer mentors with two to three selected mentees and participants asked to take part in a minimum of six monthly group calls. Groupings are determined by interest: Regulatory, Quality and Operations, Basic Science, Clinical, Commercialization and geographical location.

To ensure that the CGT field can provide passionate minds to facilitate the expected growth, societies and organizations globally are dedicating resources to train and educate future professionals and visionaries. The International Society for Cell and Gene Therapy (ISCT) developed the [ESP Committee](#) to promote networking, educational programming and mentoring for up-and-coming professionals while developing future leaders for the industry. Through this program, ISCT connects these enthusiastic ESPs with industry leaders to build a network of strong relationships and a tight-knit web that holds together the cell and gene therapy field as well as promote connection, engagement and, ultimately, the development of new and safe cell and gene therapies for patients.

The program provides for a strong future for ISCT and CGT. Mature leaders have a need to pass along all of the valuable knowledge they have gained so that ESPs at all stages of their professional development can evolve into our future leaders.

Getting Started:

After responding to the request for mentors and interested ESP members, the ESP Committee selected J. Wade Atkins as mentor to Jay Tanna and Dr. Fenlu Zhu as the cohort for the ESP Mentoring for Quality Assurance and Regulatory Affairs (QA/RA). The formal mentoring period was from November 2019 through June of 2020

Cellular and gene therapies are rapidly expanding. The past year especially has been a remarkable one for translation for these therapies with FDA's approval of CAR-T therapies and the starting of many pivotal trials. As the field is growing, it also brings a number of challenges for quality assurance and regulatory professionals. The ESP members were eager to be paired with a practicing Quality and Regulatory Specialist with more than 30 years of experience. Regulations are pivotal for cell and gene therapies as they define criteria for product safety, identity, purity, potency and efficacy. The mentoring program has provided an excellent opportunity, particularly being able to learn from a regulatory expert and to be networking with colleagues working in this field.

Our Approach:

In our kick-off call in November, we discussed how to schedule our meetings so that we can have the most productive and efficient interactions. We had a lengthy initial call about creating a safe and nurturing space with freedom to ask questions and to share details of real quality or regulatory situations within our institutions without fear of loss of confidentiality, judgmental comments or regulatory or accreditation reprisal. We agreed that a 30-minute call every two weeks would best fit our hectic schedules and provide time to review a Quality Management System concept and ask relevant questions of each other. We started our meetings with a review of one of the "pillars of a defined quality management system". This approach allowed for an open discussion about policies, processes or procedures for how each facility has implemented this quality system aspect. With encouragement to think outside the box or outside the current systems in place at respective facilities, we all were asked to determine if improvements could be implemented into our existing Quality Management Plans. This mentored exercise helped us find possible gaps in our own program and improve it. Seeing things differently, hearing different approaches and applying adaptation is very important in this rapidly changing field.

Successes and Suggestions:

All three participants have determined the mentoring project to be a success. The approach to review each essential element of a robust quality system followed by questions and open, safe discussion (no question was allowed to be labeled as a dumb question) allowed personal growth and program development.

- One member was able to correlate how the day-to-day quality assurance activities fit into the existing policies, processes and procedures. For example, the correlations between audit findings linked to training and competency systems or the linkage between implementing safety goals into facility design in order to make work space, equipment and final products safe for donors, patients, visitors and employees. Facility design is more than just clean room space! This enhanced the understanding of the importance of each quality system and its relationship to others, like putting together a jigsaw puzzle.
- One participant found the discussion about change control very useful and has revised their facility's Quality plan with lessons learned.
- In one of the sessions, we shared elements of each facility's disaster plan. Shortly thereafter, the review helped us all to be better positioned to more quickly respond to the unprecedented crisis and implementation of COVID19 containment strategies.

Since the beginning of this mentoring program, participants have been encouraged to collate thoughts and written questions between meetings to include both regulatory and quality questions. This discussion of real concerns provided reinforcement of the Quality and Regulatory Systems discussions.

Any successful program understands the necessity of Process Improvement, and this concept can be applied to this experience.

- It may have been beneficial to be able to meet in person. Virtual meetings were functional, and while they worked well during the social distancing for COVID19 containment, there may have a loss of initial bonding and building trust.
- A larger cohort may have presented a larger variety of approaches to implementation of the quality principles. The addition of a member from industry may have changed the dynamic on regulatory requirements. Diversity in member experience can provide variety in approaches and dialogue.

Future Networking Plan:

This cohort has committed to continue to use this relationship as a networking opportunity. All will continue to reach out beyond the formal mentoring period to discuss new ideas, ask opinions and share experiences. All feel more confident and comfortable now to have internal and external discussions about quality and regulatory related issues with a greater emotional maturity. We are also committed to finding the next cohort so that the network can be expanded.

Future of the ESP Mentoring Program:

The ESP Mentoring Program brings many rewards. Mentors can provide valuable contributions to the longevity of both the emerging leaders and the professional society. As the rate of medical breakthroughs using cell-based drug products continues to rise, programs such as ESP

mentoring may help sustain or accelerate that growth. The goal to quickly bring effective, safe products to market is realized through endeavors such as these educational opportunities. The mentoring program should continue as this is a great platform for early stage professionals to be directly mentored by industry experts and learn from their experience and may provide mentors with satisfaction that they are contributing in an administrative way and not just scientifically.

The members of this cohort are in agreement that: a) it was valuable experience to all, b) breaking up the meetings to smaller sessions made the meetings more manageable with other workload and commitments but also provided a platform to be succinct and participating, c) we would highly recommend participation to our peers and colleagues and d) we would all participate again if given the chance.

Summary:

The ESP Mentoring program for QA/RA professionals was a success! The novel platform for shorter meetings worked well. A fundamental element of this success was creating a safe space for frank discussions by establishing strict confidentiality and prohibiting judgmental comments. The concept of reviewing a quality system and discussing for one half of the allotted meeting time followed by discussion of its application to individual facility issues was a valuable experience for learning and for work productivity. The experience was rewarding to both the mentor and ESP members but is also viewed as the start of an enhanced network.