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Tom Layloff Announced as CASSS Hancock Award Winner for 2019

CASSS has honored Tom Layloff, PhD with its prestigious Hancock Award for Outstanding Achievements in CMC Regulatory Science.

This annual award recognizes outstanding and sustained contributions in the field of regulatory science. Layloff was announced as the 2019 honoree during CASSS’s 23rd Symposium on the Interface of Regulatory and Analytical Sciences for Biotechnology Health Products (commonly referred to as WCBP), held in Washington, D.C., January 29-31.

“I am honored, but I don’t need an award,” Layloff said after accepting the award, “Being here at the meeting today, I see many of those young investigators who came up through the FDA, now as leaders in their companies. WCBP has been an integral part of their careers,”

In his comments to introduce this year’s honoree, CASSS President Wassim Nashabeh shared highlights of Layloff’s long career. Among his achievements:

- He started his career as a professor of Analytical Chemistry at the University of Kansas.

- He was scientific advisor and eventually director of the National Center for Drug Analysis in St. Louis for over 20 years. He is largely credited for developing the center into the FDA's leading pharmaceutical testing laboratory in the nation.
- He was Director of Regulatory Standards at FDA, CDER.
- He was US Pharmacopeia Vice President and Director of the Pharmaceutical Standards Division. He was elected to serve two five-year terms on the USP Committee on Revisions. He chaired chapter subcommittees and was a member of the reference standards committee.
- He served on the key FDA advisory committee including the Manufacturing Advisory Sub-Committee and was Past Chair of the Pharmaceutical Analytical Technology Sub-Committee. These committees were advisory to FDA, CDER in their development of guidance documents which address the incorporation of new technologies into the approval and inspection processes.
- He has vast knowledge on supporting non-profit organizations in enabling access to safe and affordable medicine. He was part of MSH (Management Sciences for Health) as a Principal Program Associate in the Center for Pharmaceutical Management on the Bill and Melinda Gates funded SEAM projects for Tanzania.
- He also participated as a Senior Environmental Advisor, Partnership for Supply Chain Management (PFSCM) and technical advisor for FHI 360 (Family Health International) Product Quality and Compliance Division. His work resulted in timely availability of critical and affordable medicines to patients worldwide, in many instances, for unmet medical needs.

“You always know where you stand with Tom.” Nashabeh said, speaking of both interactions within the context of executing the WCBP Symposium and issues related to the current state of CMC/Regulatory.

“At the time, our inspectors were seeing unbelievable things in the early biologics labs. I saw WCBP as an opportunity to educate industry on FDA expectations,” Layloff said.

Dr. Layloff continues to play an important role in bringing medicines to those who need them through work as Technical Advisor, FHI 360 Product Quality and Compliance Division (fhi360.org); Senior Environmental Advisor, Partnership for Supply Chain Management (PFSCM, pfscm.org); and Principal Technical Advisor, Pharmaceutical Health Technologies Division, Management Sciences for Health (MSH, msh.org).

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About CASSS

CASSS is a not-for-profit professional scientific society made up of over 4,000 industry, academic, and regulatory professionals. CASSS is dedicated to facilitating the sharing of resources, information, and best practices to advance scientific knowledge for the benefit of its members and the public at large. Membership is complimentary and is open to all who support the objectives of the Society and are willing to contribute to the achievement of those objectives.