

Quality Business Leadership Summit

1st May 2024 TU Dublin, Grangegorman

Join senior executives and thought leaders in the dialogue on...

- How quality can be owned by all employees in the organization
- Ways to actively engage employees in quality improvements
- Learning to speak compliance in financial terms
- How the quality system can be turned into an engine of value creation
- How confidence in quality management can be improved

Welcome | Opening Remarks | Morning Session

Location: St. Laurence's

830-900	<i>Arrival & Registration @ St. Laurence's</i>	
900-910 10 min	Welcome Address	Prof. Declan McCormack Head of School, TU Dublin
910-925 15 min	Opening Remarks	Anders Vinther , Founder & CEO, QBA Colin Hughes , Head of School, TU Dublin
925-945 20 min	Keynote: Working towards a Global Quality Dossier – Quality leaders turning concept into possibility	Lorraine Nolan , CEO, HPRA
945-1020 35 min	Keynote: Taking a Stand for Pharmaceutical Quality	Janet Woodcock , former Director, CDER & Acting Commissioner, US FDA
Morning Coffee Break & Networking (1020-1040 20 min)		
1040-1110 30 min	Engaging employees in a highly regulated industry	Holger Rathgeber , CEO, NYT best selling author, Affiliate Kotter Inc
1110-1140 30 min	ICH Q9(R1): The Quality Leader's Opportunity for Effective, Patient-centric Decision-making	Kevin O'Donnell HPRA, ICH Q9(R1) Rapporteur
1140-1220 40 min	Panel Discussion with Keynote & Morning Session speakers <i>Moderator: Anders Vinther</i>	

Lunch Session

Location: Central Quad 008

1220-1230	<i>Transfer from St. Laurence's to CQ008 – please take all belongings with you</i>	
1230-1255 25 min	GMP Compliance, Quality Assurance, and Business Synergy	Rick Friedman , Deputy Director Manufacturing Quality, CDER, U.S. FDA
Lunch & dialogue on Quality Business Leadership (100-200 60 min)		
200-215	<i>Return transfer from CQ008 to St. Laurence's hall (remember your belongings!)</i>	

Afternoon Session | 215-515 pm

continued on reverse

Location: St. Laurence's

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Afternoon Session

Location: St. Laurence's

215-235 20 min	Report out: Lunch dialogue	Anders Vinther , CEO QBA Marty Lipa , PRST
235-300 25 min	Panel: Quality's role in partnering with Operations <i>Panelists:</i> Cathal Elliott (Amgen), Tracy Walshe (Pfizer), Maureen Larkin (Alexion/AZ)	<i>Panel Moderator</i> Paul O'Neill , EVP Quality & Operations - Specialty Brands
300-325 25 min	Optimising the value of quality through proactive Quality management	Jane Wyatt , Global Head of Quality Operations, Alexion
Afternoon Break & Networking (325-345 20 min)		
345-410 25 min	How to speak cGMP AND \$GMP: compliance understood by senior management	Craig Elliott , former CFO PDA, and <i>presented by Anders Vinther</i> , Founder & CEO QBA
410-435 25 min	The Quality Professional as The Business Leader	Pat O'Mahony CEO, Mapat Management Consultants
435-505 30 min	Panel Discussion with Afternoon Session speakers <i>Moderator: Janet Woodcock</i>	
505-515 10 min	Closing remarks	Anders Vinther CEO QBA

Join us for a post-summit social hour for continued networking & dialogue on **Quality Business Leadership**

Sponsored by CAI

Immediately following @ 5:30 – 6:30 on campus at TU Dublin (room to be announced)

Quality Business Leadership Summit Planning Committee

Anders Vinther, Founder & CEO of QBA, and co-lead 1VQ for PAC
Anne Greene, Professor TU Dublin & Director PRST
Marty Lipa, TU Dublin, PRST & Senior KM Consultant
Valerie Mulholland, PRST & GMP Services
Donncadh Nagle, PRST & TU Dublin



The 6 Quality Business Leadership Traits