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SAE Media Group Proudly Presents the 9th Annual Conference on...

PRE-FILLED SYRINGES AND INJECTABLE DRUG DEVICES

WEST COAST

9 - 10 JUN 2025

**ADVANCING COMBINATION PRODUCT DEVELOPMENT
TO ELEVATE PARENTERAL DRUG DELIVERY**

San Diego Marriott La Jolla, CA, USA



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PRE-FILLED SYRINGES AND INJECTABLE DRUG DEVICES WEST COAST

JUNE 9-10, 2025



KEY REASONS TO ATTEND:

- **Foster Collaboration and Innovation in Injectable Drug Delivery:** Engage with industry leaders such as AstraZeneca, Gilead and Alnylam to explore collaborative opportunities, stay informed about emerging technologies, and address challenges such as large volume delivery.
- **Stay Updated on Global Regulatory Trends:** Participate in discussions about evolving EU and US regulations, including the latest requirements for digital health technology registration from Merck.
- **Optimize Combination Product and Drug/Device Integration:** Gain strategic insights into how to enhance combination product manufacturing and effectively align innovation for advanced therapeutic delivery, with insights from the likes of Ionis, Inovio and Bexson Biomedical.
- **Enhance Human Factors Understanding:** Gain practical knowledge from JnJ on human factors best practices, and apply effective testing and validation approaches for combination products.

Dear Colleagues,

As Chair of the conference, it is my pleasure to welcome you to SAE's Pre-Filled Syringes and Injectable Drug Devices West Coast Conference, taking place on the 9-10 June 2025.

The 9th annual conference will gather leading experts in combination products and injectable drug delivery. Across two days, we will explore the latest advancements in device design and development to enhance drug delivery and improve patient outcomes.

The agenda will feature key insights into the latest technologies for large-volume drug delivery, advanced injectable delivery modalities, and strategies for leveraging platforms to accelerate development. New for 2025, the agenda will include California-based biotech dedicated keynotes and panel discussions. Attendees will also gain critical updates on device usability and tolerability, the evolving US and EU regulatory landscapes, and innovations in combination product lifecycle management and primary packaging. These subjects will be addressed through industry outlooks and case studies, providing a platform to benchmark against the latest advancements and best practices in the field.

We look forward to welcoming you to this must attend event in June and to fostering meaningful discussions that advance innovation in injectable drug delivery.

Yours Sincerely,



Amin Sedighiamiri,
Director, Device Development,
AstraZeneca

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PRE-FILLED SYRINGES AND INJECTABLE DRUG DEVICES WEST COAST



WHAT TO EXPECT FOR 2025

Bringing together expertise from individuals across the combination product and injectable drug delivery field...

200+ Attendees

25+ Speakers

45+ Big Pharma and Biotech Companies in Attendance

California-based Biotech
Dedicated Keynote Sessions and Panel Discussions

FREE for Pharma and Biotech to Attend*

Featured Speakers Include:



Alasdair Young,
Senior Director
– Device Engineering,
Gilead Sciences



Amin Sedighiamiri,
Director, Device Development,
AstraZeneca



Aniket Badkar,
Director, Formulation and Drug
Product Development,
Vir Biotechnology



Bernie Huyghe,
CTO,
Candid Therapeutics



Christina Rabolli,
Principal Engineer,
Bristol Myers Squibb



Monica Swinney
Sr. Director, New Product Planning
& Drug Delivery Innovation
Gilead Sciences



Daphne King,
Associate Director,
Acadia Pharmaceuticals



EJ Brandreth,
Senior VP, Quality,
Inovio



James Wabby,
Executive Director, Head of Regulatory
Strategy, Emerging Technologies
and Combination Products, **AbbVie**



Kevin Zen,
Senior Director,
IGM Biosciences



Kinsuk Shah,
Combination Product Steward,
Boehringer Ingelheim



Mitch Zhao,
Distinguished Engineer,
JnJ Innovative Medicine



Phil Estepa,
Executive Director,
Pharmaceutical Development,
Ionis Pharmaceuticals



Casey Dean,
Senior Manager, Device and
Packaging Development,
Tolmar Inc



Renato Ravello,
Director,
Genentech



Sheldon Moberg,
Senior VP Drug Delivery,
Bexson Biomedical



Shiang Gwee,
Director, Drug Product
Development,
Altrubio



Sujit Basu,
Vice President & Head,
Pharmaceutical Development,
Ionis



Tina Rees,
Director,
Regeneron Pharmaceuticals



Wenjing Wang,
Associate Director,
Merck



Greg Salamone
Principal Human Factors Engineer
Regeneron Pharmaceuticals Inc



Angela Muriset
Director, Human Factors Center
of Excellence - Combination
Product Development, **AbbVie**

and more...

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PRE-FILLED SYRINGES AND INJECTABLE DRUG DEVICES WEST COAST

DAY ONE | MONDAY JUNE 9, 2025

08.00 Registration & Coffee

08.50 Co-Chairs' Opening Remarks
Amin Sedighiarni, Director, Device Development, **AstraZeneca**

DEVICE INNOVATIONS FOR THE FUTURE OF INJECTABLE DRUG DELIVERY

09.00 OPENING ADDRESS

Accelerating Injectable Innovation: An overview of emerging technologies for injectable drug delivery

- Reviewing the current landscape of emerging technologies to support injectable drug delivery
- Assessing industry challenges in the emerging technologies space and potential ways to overcome these
- What are the current gaps in industry and what areas should be focused on to accelerate innovation?
- Opportunities for development of more effective subcutaneous devices and digital apps

James Wabby, Executive Director, Head of Regulatory Strategy, Emerging Technologies and Combination Products, **AbbVie**



09.30 Session Reserved for Suttons Creek



10.00 Developing Large Volume Injection Devices: Enhancing Subcutaneous Drug Delivery and Patient Experience for Successful Commercial Launch

- Designing user-centric devices for optimal delivery of novel therapeutics, including sustained release and large-volume formulations
- Maximizing therapeutic efficacy by focusing on dose accuracy, safety, and user convenience
- Real-world insights through a case study on the development and deployment of a successful wearable device
- Sustainability implications of such devices and balancing trade offs

Renato Ravanello, Director, **Genentech**



SHL MEDICAL

10.30 Morning Coffee

11.00 Session Reserved for SHL Medical

11.30 Mapping the Parenterals Pipeline to Platform Opportunities & Building a Compelling Business Case

- A first-principles derived design space for leading pre-filled syringes, autoinjectors, and on-body injectors
- Primary container selection, siliconization, & drug stability considerations
- Making the business case for platform development: cost, revenues, time, and competitive advantage

Monica Swinney, Sr. Director, New Product Planning & Drug Delivery Innovation, **Gilead Sciences**



12.00 Session Reserved for Credence MedSystems

12.30 Advancing Injectable Devices: Balancing Innovation, Scalability, and Sustainability

- Emerging Trends in Injectable Devices: Exploring smart technologies, connectivity adoption, and patient-centric designs that enhance adherence and user experience
- Large-Volume Delivery Challenges: Addressing engineering innovations and strategies to deliver high-viscosity drugs and biologics effectively and comfortably
- Advancing Sustainability in Design and Manufacturing: Analyzing the push toward eco-friendly materials, recycling solutions, and sustainable lifecycle management practices in device production
- Regulatory and Market Dynamics: Understanding regulatory developments from the past year such as the essential drug delivery outputs (EDDO) guidance and market response
- Scalability: Experiences and approaches to scale up the development and manufacturing of injectable devices, focusing on maintaining precision, reliability, and regulatory compliance while addressing the growing demand for complex drug delivery systems

Panel Moderator:

Amin Sedighiarni, Director, Device Development, **AstraZeneca**

Panelists:

Phil Estepa, Executive Director, Pharmaceutical Development, **Ionis Pharmaceuticals**

Alasdair Young, Senior Director – Device Engineering, **Gilead Sciences**

Mitch Zhao, Distinguished Engineer, **JNJ Innovative Medicine**



13.10 Networking Lunch

14.10 Session Reserved for Haselmeier



14.40 CALIFORNIA-BASED BIOTECH KEYNOTE

Development and commercialization of innovative medical devices and combination products

- The importance of treating a combination product as a system and initiating the development effort early in the program
- Understanding key device constituent part selection criteria to meet the combination product Target Product Profile (TTP)
- The benefit of wearable infusion pumps to support a shift from in-clinic IV administration to home subcutaneous therapy administration
- Criticality of drug/device integration including contact material assessment, fill/finish processing, drug properties, and primary container handling

Sheldon Moberg, Senior VP Drug Delivery, **Bexson Biomedical**



CONSIDERATIONS FOR SUCCESSFUL DRUG/DEVICE INTEGRATION

15.10 Combination Product Innovation and Alignment for Advanced Therapeutic Delivery

- Balancing the timing and scale of innovation in combination product delivery solutions to meet patient and clinical demands
- Exploring a case study on the journey from concept to approval, highlighting regulatory, design, and testing insights for combination products
- Reviewing opportunities for scaling processes and fostering innovation in response to the growing demand for advanced modality drugs
- Shaping the future of injectable delivery systems through collaboration and cross-disciplinary innovation

Sujit Basu, Vice President & Head, Pharmaceutical Development, **Ionis**

15.40 Session Reserved for Mitsubishi Gas Chemical



16.10 Afternoon Break

16.40 CALIFORNIA-BASED BIOTECH PANEL DISCUSSION
Tackling injectable delivery of advanced modalities

- Understanding the requirements for effective parenteral delivery of advanced modalities including DNA, RNA and Cell and Gene Therapies
- Tackling challenges specific to novel modality formulations including cold storage, stability, high volume and high viscosity
- Keeping pace with the growing demand for advanced modality drugs – scaling formulation and delivery processes
- Looking to the future – how can the growing demand for new modality drugs drive innovation within the injectable sector

Panel Moderator:

Sujit Basu, Vice President & Head, Pharmaceutical Development, **Ionis**

Panelists:

EJ Brandreth, Senior VP, Quality, **Inovio**

Aniket Badkar, Director, Formulation and Drug Product Development, **Vir Biotechnology**

Shiang Gwee, Director, Drug Product Development, **Altrubio**



17.20 Session Reserved for Zeon



DELVING INTO REGULATORY AND CMC BEST PRACTICES FOR SUCCESSFUL PRODUCT APPROVAL

17.50 CALIFORNIA-BASED BIOTECH KEYNOTE

The evolving Regulatory Landscape for Drug-Device Combination Products: A CMC Perspective

- Moving to MDR: implementation timelines and new requirements
- Replacement of IVDD with IVDR and implications on legacy devices
- Transitioning from lab developed tests to companion diagnostics
- Case study example of a successful transition of CMC processes in line with new regulations

Daphne King, Associate Director, **Acadia Pharmaceuticals**



18.20 Chair's Closing Remarks and Close of Day One

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PRE-FILLED SYRINGES AND INJECTABLE DRUG DEVICES WEST COAST



DAY TWO | TUESDAY JUNE 10, 2025

08.15 Registration & Coffee

08.50 Co-Chairs' Opening Remarks

Amin Sedghiamiri, Director, Device Development, AstraZeneca

ADVANCEMENTS IN COMBINATION PRODUCT DEVELOPMENT APPROACHES

09.00 OPENING ADDRESS

Enabling Fast Scale-Up and Successful Design Transfer for Injectables

- Development of a transferable manufacture process to allow for quick scale up post-approval
- Supplier selection and management considerations in device development to assist in-built scalability and transferability
- Building a bridge between design and manufacturing

Phil Estepa, Executive Director, Pharmaceutical Development, Ionis Pharmaceuticals



09.30 Regulatory registration for digital health technologies (DHTs) as part of combination products

- Overview of digital health technologies and their integration into combination products, highlighting key trends and examples
- Regulatory Framework for DHT Registration: Key considerations, global regulations, and pathways for obtaining approval for DHTs as part of combination products
- Ensuring compliance through robust validation, cybersecurity measures, and real-world evidence for DHTs in combination products
- Challenges and opportunities in the registration process

Wenjing Wang, Associate Director, Merck



10.00 Session Reserved for Crux Product Design

10.30 Morning Coffee

11.00 Combination Product Lifecycle Management - Efficient Communication and Collaboration

- Strategies for ensuring seamless collaboration and communication between cross-functional teams throughout the submission process to meet compliance requirements
- Best practices for tracking, assessing, and implementing product changes while maintaining regulatory alignment
- Case study demonstrating the impact of a well-defined, cross-functional approach in combination product management

Desiree Daniels, Principal Specialist, CMC Management and Regulatory Compliance, Boehringer Ingelheim



11.30 Terminal Sterilization of Injectable Drugs, Devices and Prefilled Syringes

- Terminal radiation sterilization of:
- Injectable Drugs
- Lyophilized powders
- Liquids
- Drug delivery devices
- Prefilled syringes and vials

Sep Mohseni, Director of Sales Operations, SteriTek



12.00 Streamlining Safety Syringe Development: A Case Study in Collaborative Design Verification

- Exploring how strategic partnerships can accelerate safety syringe design and development
- Practical approaches to optimizing verification workflows for regulatory compliance and efficiency
- Insights into overcoming common hurdles in safety device development programs
- Case Study with lessons learned and best practices from a successful safety syringe program

Christina Rabolli, Principal Engineer, Bristol Myers Squibb

12.30 Optimizing Combination Product Development: Leveraging Platform Devices for Enhanced Efficiency and Innovation

- Exploring the concept of platform devices and how they can serve as a foundation for streamlined development processes
- Strategies for integrating platform devices into the product development lifecycle to reduce time to market, minimize development costs, and improve overall project management
- How platform devices can accelerate innovation by enabling rapid prototyping, iteration, and customization to meet specific patient needs and market demands
- Overcoming Challenges: Addressing common hurdles and managing complexities associated with combination product development

Casey Dean, Senior Manager, Device and Packaging Development, Tolmar Inc

13.00 Networking Lunch

14.00 Session Reserved for EdgeOne Medical



IMPLEMENTING PATIENT CENTRIC DESIGN INTO INJECTABLE DEVELOPMENT

14.30 AFTERNOON KEYNOTE

Device Usability and Tolerability Assessment from Clinical Trials

- Analyzing how usability and tolerability differ across diverse patient populations in clinical trials
- Key Influences on User Experience: Exploring design, training, and demographic factors affecting outcomes
- Strategies to align device design with real-world patient needs and feedback
- Leveraging trial data to improve device performance and patient adherence

Mitch Zhao, Distinguished Engineer, JnJ Innovative Medicine



15.00 Assessing human factors testing and validation approaches for combination product platforms

- Ways to generate high-value results to engage constructive design and development decision making
- Best practices on platform human factors formative and validation protocol development
- Factors to consider for balancing requirements (e.g. technical, commercial, user needs)

Tina Rees, Associate Director, Human Factors, Regeneron Pharmaceuticals

15.30 Enhancing User Acceptance of Injection Devices: Human Factors Strategies for Success

- Integrating human factors to drive user acceptance – How early-stage human factors research informs design decisions that improve user confidence, trust, and adoption
- Identifying barriers to user acceptance through human factors research and design activities
- Leveraging user feedback to refine injection device user
- Ensuring instructions and packaging support ease of use and adherence, fostering a positive user experience

Angela Muriset, Director, Human Factors Center of Excellence - Combination Product Development, AbbVie

16.00 Afternoon Break

MAXIMISING MANUFACTURING AND QUALITY FOR INJECTABLE DEVICES

16.30 Session Reserved for Datwyler



17.00 CALIFORNIA-BASED BIOTECH PANEL DISCUSSION
Partnering with biotech's: fostering innovation through collaboration

- What makes a successful partnership? Identifying key criteria for successful collaboration between biotechs and big pharma or suppliers to aid parenteral delivery of novel therapeutics.
- Challenges in developing delivery systems for drug candidates as they progress through critical R&D stages
- Uncovering the power strategic partnerships have to accelerate combination products through pre-clinical and clinical development, on to the shelf
- Case studies showcasing partnership success stories

Panelists:

Sheldon Moberg, Senior VP Drug Delivery, Bexson Biomedical
Kevin Zen, Senior Director, IGM Biosciences
Bernie Huyghe, CTO, Candid Therapeutics



17.30 Chair's Closing Remarks and Close of Day Two

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SHL MEDICAL

SHL Medical is a pioneering leader in self-injection solutions, such as autoinjectors. Driven by our purpose of "enabling patients' independence", we partner with leading pharma and biotech companies to develop self-injection systems and digital solutions that enhance patients' treatment experience and quality of life. Our customers benefit from our proven track record and scalable, global manufacturing excellence, with locations in Switzerland, USA, Sweden, and Taiwan. By focusing on innovation, we challenge the status quo and shape the future of state-of-the-art drug delivery. We cover the entire drug delivery value chain, providing piece of mind through our end-to-end services, from design, development, to final assembly, labeling, and packaging. www.shl-medical.com



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Suttons Creek is pharma's device team. Any company adopting combination product technology needs an experienced combination products team working alongside their drug team, including specialists in areas like quality, regulatory, vendor selection and management, systems engineering, risk management, clinical development, and commercialization. Suttons Creek has over 650 years of combined experience and 120+ combination product projects under its belt, with a talent pool of subject matter experts that specialize in all aspects of combination product development from strategic planning through device development to launch and postmarket activities. We can be any or all things combination product to a client, consulting hour by hour or engaging in strategic partnerships to achieve milestones, lift roadblocks, fill knowledge gaps, and drive program success. www.suttonscreek.com

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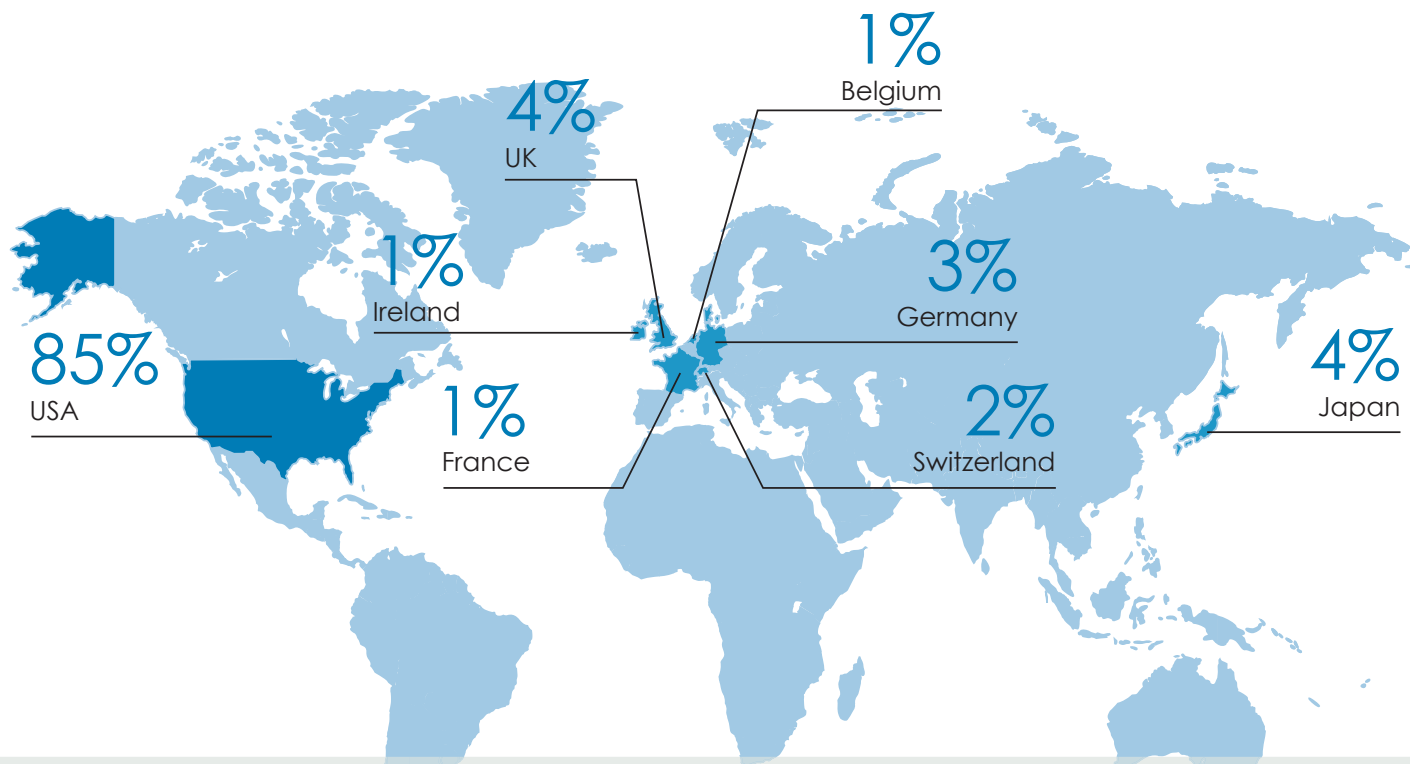
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AUDIENCE BREAKDOWN



PFS Portfolio Testimonials from Past Speakers and Attendees

“Thank you to the SAE Media Group Pharma Team for organizing the event and allowing such great networking between leaders and experts in the medical device fields”

- SENIOR DIRECTOR, BAYER

“Really engaging talks from experienced leaders in the medical device and pharmaceutical industry with a shared passion to improve the patient experience”

- SENIOR HUMAN FACTORS ENGINEER, TEAM CONSULTING

“A well-structured agenda that has matched greatly the needs of a well-identified target group within the life science community, which created a unique kind of 'family atmosphere' thus fostering information sharing and productive discussions.”

- GLOBAL MEDICAL DEVICE LEADER, SANOFI

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Please complete fully and clearly in capital letters. Please photocopy for additional delegates.

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Surname:

Job Title:

Department/Division:

Company/Organisation:

Email:

If you would like to continue to receive email updates about our events, please tick ☐

Company VAT Number:

Address:

Town/City:

Post/Zip Code: Country:

Direct Tel: Direct Fax:

Mobile:

Switchboard:

Signature: Date:

I agree to be bound by SAE Media Group Terms and Conditions of Booking

ACCOUNTS DEPT

Title: Forename:

Surname:

Email:

Address (if different from above):

Town/City:

Post/Zip Code: Country:

Direct Tel: Direct Fax:

VENUE Horton Grand Hotel, San Diego, CA, USA

☐ Please contact me to book my hotel
Alternatively call us on +44 (0) 870 9090 711,
email: events@saemediagroup.com or fax +44 (0) 870 9090 712

BOOKING SUMMARY

Terms and Conditions of Booking

Payment: Our payment terms are as follows: if booking 16 days or more before the conference, payment should be made within 14 days of date of invoice. If booking 15 days or less before the conference, payment is due on receipt of invoice and must be received no later than the last working day prior to the event start date. In the event, that the customer has not paid by the last working day before the event, we reserve the right to obtain card details for payment to be taken for the full invoice amount or as a guarantee of payment. Access to the Document Portal will not be given until payment is received.

Substitutions/Name Changes: If you are unable to attend you may nominate, in writing, another delegate to take your place at any time prior to the start of the event. Two or more delegates may not 'share' a place at an event. Please make separate bookings for each delegate.

Cancellation: If you wish to cancel your attendance at an event and you are unable to send a substitute, then we will refund/credit 50% of the due fee, providing that cancellation is made in writing and received 28 days prior to the start of the event. Regrettably cancellation after this time cannot be accepted. We will however provide the conferences documentation via the Document Portal to any delegate who has paid but is unable to attend for any reason. Due to the interactive nature of the Briefings, we are not normally able to provide documentation in these circumstances. We cannot accept cancellations of orders placed for Documentation or the Document Portal as these are reproduced specifically to order. If we have to cancel the event for any reason, then we will make a full refund of your payment but disclaim any further liability.

Alterations: It may become necessary for us to make alterations to the content, speakers, timing, venue or date of the event compared to the advertised programme. By registering for this event, you are providing us with some personal details, including an email address. Smi Group Ltd Trading as SAE Media Group will process that information as described in our privacy policy <https://www.smgconferences.com/privacy-legals/privacy-policy/> Part of the value of our events is in the networking and relationship building opportunities. To support this, we may facilitate professional introductions on-site at our events.

CONFERENCE PRICES

I would like to attend: (Please tick as appropriate)

Price

IN-PERSON ATTENDANCE

☐ Standard Price		\$2498.00
☐ Register and pay by February 27	Save \$400.00	\$2098.00
☐ Register and pay by March 27	Save \$200.00	\$2298.00
☐ Register and pay by April 24	Save \$100.00	\$2398.00

Big Pharma and Biotech Representatives

FREE*

* Please note, all registrations are subject to approval by SAE Media Group. Anyone registering at the Pharma and Biotech rate must have a public drug pipeline and provide a working company email address. Failure to do so will result in a refusal of entry to the event, or a requirement to purchase a ticket at a different rate. Please note, the pharma/biotech company rate does not apply to service/solution providers. Please contact katie.ogden@saemediagroup.com to register your interest.

Please note that the above ticket price includes access to all approved distributable PDF presentations post-event, priced at \$99. To opt out, please contact via email: delsalesuk@saemediagroup.com or call: +44 (0) 207 827 6000.

PROMOTIONAL LITERATURE DISTRIBUTION

☐ Distribution of your company's promotional literature to all conference attendees	£999.00	+ VAT
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As an added benefit of attending this conference, check here to receive a free subscription to Medical Design Briefs, the leading new technology magazine for bio-medical professionals. Choose either: ☐ Print (U.S. only) ☐ Digital

The conference fee includes on-demand access to the Document Portal. Access information for the document portal will be sent to the e-mail address provided during registration. Details are sent within 7 working days post-conference.

DOCUMENTATION

I cannot attend but would like to Purchase access to the following Document Portal

Price

☐ Access to the conference documentation on the Document Portal	£699.00	+ VAT
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VAT

VAT at 20% is charged on Document portal and literature distribution for all UK customers and for those EU customers not supplying a registration number for their own country here.

PAYMENT

Payment must be made to **SMi Group Ltd**, and received before the event, by one of the following methods **quoting reference P-446 and the delegate's name. Bookings made within 7 days of the event require payment on booking, methods of payment:**

☐ UK BACS	Sort Code 300009 , Account 11775391
☐ Wire Transfer	Lloyds TSB Bank plc, 39 Threadneedle Street, London, EC2R 8AU Swift (BIC): LOYDGB21013 IBAN GB75 LOYD 3000 0911 7753 91
☐ Cheque	We can only accept US Dollar Cheques drawn on a US Bank.
☐ Credit Card	