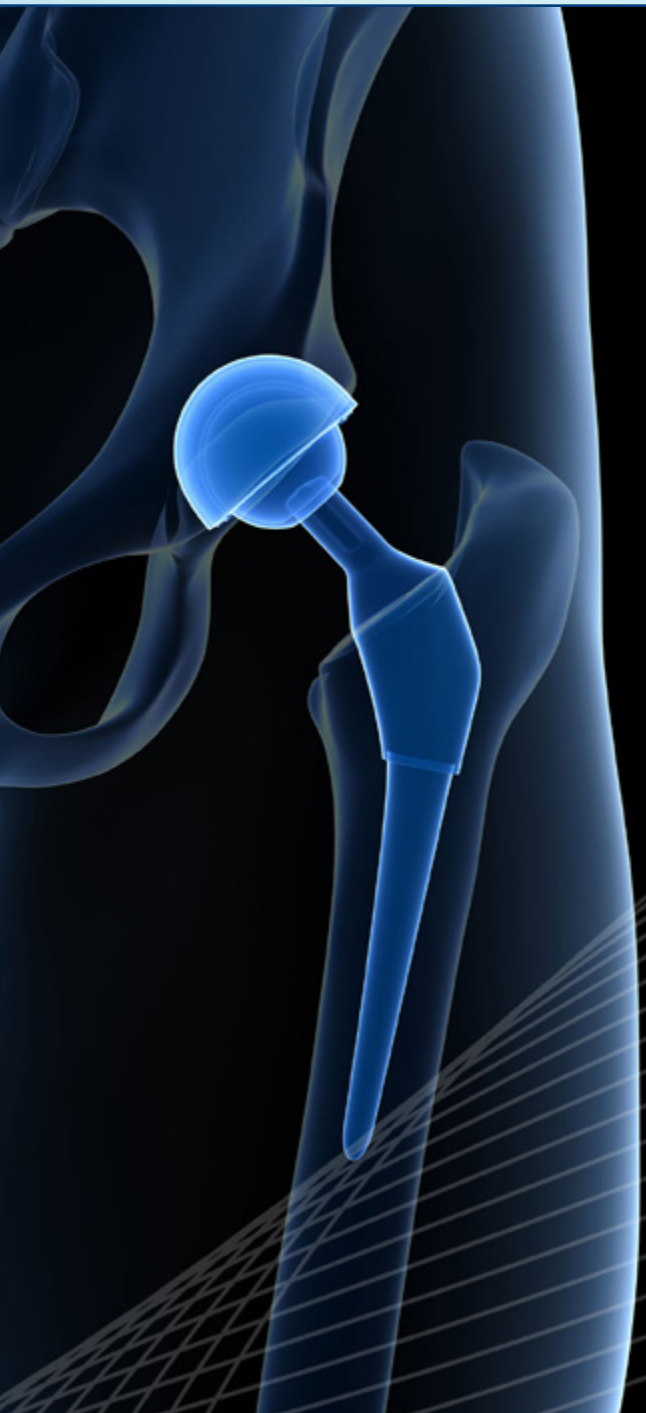
Association of University Technology Managers®
Advancing Discoveries for a Better World®

AUTM
Business Development Course
Medical Devices



November 17 – 18, 2015

Hyatt Regency Dallas
Dallas, TX USA

Join us in Dallas!

About the AUTM Business Development Course

This course provides an in-depth look at the medical device market including the pre-clinical phase, clinical and regulatory phase, health economics and reimbursement, legal and business issues encountered when commercializing technologies in the medical device space. The AUTM Business development course is supported by the Wallace H. Coulter Foundation.

About AUTM

The Association of University Technology Managers is a nonprofit organization dedicated to promoting, supporting and enhancing the global academic technology transfer profession through internal and external education, advocacy and communications. AUTM's more than 3,200 members represent managers of intellectual property from more than 300 universities, research institutions and teaching hospitals as well as numerous businesses and government organizations.

Meeting Agenda

Tuesday, November 17

Noon – 5 p.m. **Registration**

1 – 2:45 p.m. **Overview of Medical Device Market and Technology Transfer Experience**

Instructors:
Alan R. Bentley, *Vanderbilt University*
Jamie Kemler, *Stryker*
Axel Strombergsson, *Vanderbilt Universtiy*
Julie Watson, *Marshall, Gerstein & Borun LLP*

This session will lay the groundwork for the topics to be explored in depth throughout the course. The panelists will describe the medical device market broadly, and will explore market opportunities and growth segments for new generations of devices. Programs for de-risking medical device commercial opportunities are discussed, together with policy implications of such translational research. An assessment of the impact regulatory expertise in academia will be explored. When to out-license and how to structure transactions for different classes of devices will be reviewed. This session will conclude with a report on medical device deal structures based on data from the AUTM TransACT database.

2:45 – 3:15 p.m. **Networking Break**

3:15 – 5 p.m. **Pre-Clinical Phase**

Instructors: **Bruce Gingles,** *Cook Medical*

Picking potential license winners from the academic tree requires a good eye and a probative analytical process. By its nature, academia tends to be focused on fundamental knowledge gathering rather than commercial potential. On the other hand, companies licensing technologies are looking for technology solutions to well-defined problems that have commercial potential – they seek technologies that provide value. They want to know: What's the product? Does it work? Who will buy it? What problem is being solved and why is this the optimal solution? Our objective is to present the process of technology matching to problem and need identification, along with the associated risk assessment and Proof of Concept activities, with a specific emphasis on assessing commercial value. We will approach these subjects from the perspective of licensing professionals keen on picking good candidates and making good deals.

6 – 7:30 p.m. **Networking Reception**

Meeting Agenda

Wednesday, November 18

7 – 8 a.m. **Continental Breakfast**

8 – 10 a.m. **Clinical and Regulatory Phase**

Instructor: **Robert Wanerman,** *Epstein Becker Green*

Bringing a new medical device to market in the U.S. involves multiple regulatory layers. Navigating the multiple approvals that are necessary to successfully commercialize a new device can be an expensive and time-consuming endeavor. This session will focus on those regulatory processes, with the goal of providing a better understanding of the regulators, what regulators expect from manufacturers and how to develop an effective strategy for an individual product.

The session will address coverage, coding and reimbursement systems, with an emphasis on the following:

- Designing and implementing clinical trials to generate data for use by both the Food and Drug Administration (FDA) and payers
- Compliance issues related to clinical trials, including Institutional Review Board (IRB) requirements, conflict of interest issues and fraud and abuse risks
- Reporting obligations under U.S. laws
- An overview of European Union reimbursement

10 – 10:30 a.m. **Networking Break**

10:30 a.m. – Noon **Getting Paid: The Need for Health Economics and Reimbursement**

Instructor: **Thomas Byrne,** *Boston Scientific*

Join us for this session to gain a basic understanding of the reimbursement mechanisms in the U.S. (using medical devices as the primary example).

Topics covered will include:

- What is Health Economics & Reimbursement (HE&R) and why it is important in bringing medical technology products to market
- Who the major public and private payers are in the U.S. and how/why medical technology companies must interact with them
- Overviews of the three main components of reimbursement in the U.S.: coding, coverage payment
- How clinical and economic evidence are increasingly mission critical
- How the changing healthcare environment in the U.S. is altering business models and how HE&R is evolving

Noon – 1:15 p.m. **Networking Lunch**

Over lunch, attendees will work collaboratively in groups to identify examples of unique or successful commercialization stories for medical devices, focusing on outcomes, deal structures, lessons learned or overall impact. Stories will then be shared with all attendees in an interactive manner that will lead to a deeper appreciation and understanding of the art of commercializing medical devices.

1:15 – 2:45 p.m. **Legal Issues**

Instructors: **Jeremy Kriegel,** *Marshall, Gerstein & Borun LLP*
Robert Wanerman, *Epstein Becker Green*

A university's technology transfer office is often the focal point for a wide range of regulatory matters that affect the successful commercialization of discoveries. In this session, two attorneys with extensive regulatory and compliance experience will address a wide range of topics affecting technology transfer, including:

- Maximizing potential value by building a cost-effective intellectual property foundation
- Issues and strategies for significant foreign jurisdictions
- Compliance issues arising under National Institutes of Health (NIH) and National Science Foundation (NSF) grant laws and policies
- Fraud and abuse risks
- Coordinating technology transfer into the university's compliance program

The session is intended to be interactive, and to build on best practices.

2:45 – 3 p.m. **End of Course Wrap-up, Key Learnings**

Join the instructors to tie up any loose ends, answer unaddressed issues and capture the important take home messages.

Faculty

Alan Bentley is Assistant Vice Chancellor – Technology Transfer with Vanderbilt University.

Alan has served as the director of Vanderbilt University's Center for Technology Transfer and Commercialization since 2011. Previous technology transfer experience includes directing the licensing operations at the Cleveland Clinic and the University of Virginia Patent Foundation. He is active in several professional societies, and serves on a number of corporate and community boards. Alan has been a registered U.S. Patent Agent since 1999, and is a Certified Licensing Professional.

Tom Byrne is Director of Health Economics and Reimbursement at Boston Scientific Corporation. Byrne joined Boston Scientific in 1998 as the company's second hire for its entrance into the world of reimbursement and health economics. He has since played a leading role in the formation and maturation of the company's Health Economics and Reimbursement function and its supporting infrastructure. Currently, Byrne and his team support Boston Scientific's Urology/Women's Health division. There they work to ensure that the division's products and procedures are appropriately recognized within the complex and constantly evolving reimbursement mechanisms that characterize healthcare systems around the world. In addition, Byrne and his team work to identify, compile, and disseminate the clinical and economic evidence required to demonstrate the value of these product lines to those who purchase and pay for them.

Prior to joining Boston Scientific, Byrne was with Blue Cross and Blue Shield of Massachusetts for more than a decade, where he held a variety of positions including Director of Medical Policy and Cost Containment. Byrne is a Boston native. He holds bachelors' degrees in Biology and Political Science from Boston College and an MBA from the F. W. Olin Graduate School of Management at Babson College.

Bruce Gingles is a 1977 Indiana University BA graduate, biology. Bruce was hired by Cook Incorporated in 1979 as the company's first sales representative for its newly formed Critical Care division. In 1991, he moved from California to Cook's Bloomington, Indiana, headquarters as Director, Sales and Product Development and in 1999 was named Vice-President, Cook Critical Care and Global Strategic Business Unit (SBU) Leader. In 2011, he moved into a newly-created position, Vice-President, Global Technology Assessment and Healthcare Policy. In this job, Bruce works across Cook's 10 SBUs to strengthen Cook Medical's technology pipeline, develop economic analyses for Cook products, and to foster pragmatic relationships between industry, academia and health systems.

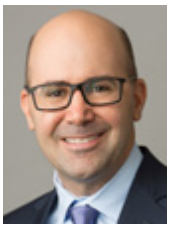
Bruce serves on the CTSI external advisory committees for Indiana University, UCSF, Ohio State University, University of Chicago and the University of Florida, and has been invited to speak about medical device invention and commercialization at more than 35 CME/CLE forums in Europe, Asia, Australia and North America. He has six issued US patents.

James Kemler is currently the VP, Intellectual Property Business Strategy for Stryker Corporation with responsibility for the development and execution of Stryker's enterprise-wide IP business strategy to include monetization activities and leadership of a cross-company network to manage relationships with technology transfer and licensing/venture offices of targeted global universities, hospitals, and government agencies. Prior to this role, Mr. Kemler was Group President, Regenerative Medicine, which focused on the clinical development of the recombinant human protein BMP-7 for its use in cartilage, osteoarthritis, and fibrotic disease. Earlier in his career at Stryker Mr. Kemler's Group President role included responsibility for the Spine, Trauma, and Development divisions, with multiple manufacturing and research operations in Europe and the U.S.

Mr. Kemler began his career at American Hospital Supply Corporation in manufacturing management in their Edwards Laboratories Division in Irvine, California (now Edwards Lifesciences). In 1983 he joined Baxter International and held management positions in Corporate Planning, the Fenwal Division, and the Pharmaceuticals Group. In 1987 he moved to Munich, Germany and assumed the role of Finance Director and later Director of Sales and Marketing for the Cardiovascular products for the Baxter Germany subsidiary. Upon his return to the U.S. in 1991, Mr. Kemler became VP of Manufacturing and later VP of Marketing and R&D for the V.Mueller Surgical Instruments division. In 1994 he joined Sabratek Corporation, a start-up medical device company, as COO. In 1995 he joined Stryker Corporation as General Manager of the Biotech division and was promoted to President of the division at the end of 1996. In 2001 Mr. Kemler was promoted to the position of Group President.

James Kemler received a B.S.E. in Biomedical Engineering from Duke University in 1979 and an M.B.A. from Harvard Business School in 1983. In 2012 he became a registered Patent Agent. He is also a Certified Licensing Professonial.

Faculty



Jeremy Kriegel is a partner and Chair of the Patent Prosecution practice of the Chicago intellectual property law firm Marshall, Gerstein & Borun LLP. Kriegel joined the firm in 2001, and concentrates on prosecution of patent applications for medical devices, including breast pumps, cardiac catheters, minimally invasive surgical instruments, tissue sealants, wound dressings, orthopedic instruments, dental instruments, ostomy and urology products, and organ donor matching systems.

Mr. Kriegel received his Bachelor of Science with distinction in Mechanical Engineering and a Management Studies Certificate with concentration in public sector analysis from the University of Rochester in New York in 1992, and his J.D. from Washington University in St. Louis in 1995, where he served on the law review editorial board. According to Chambers, Kriegel "is known for his work in medical device patents" and "he is well respected by his peers for his expertise in patent prosecution."

Axel Strombergsson joined the CTTC in December of 2014 and is responsible for providing regulatory affairs support to research teams that are developing medical devices at Vanderbilt University. Prior to joining CTTC, Strombergsson spent 12 years of his career within the medical device industry, primarily for Plasma Surgical, a medical device manufacturer developing and distributing an energy based surgical system. During his time at Plasma Surgical, Strombergsson held various engineering positions, starting as a development engineer and project manager, and later transitioning into managerial positions. These positions consisted of initially being the manager for process development at the Swedish manufacturing site, and later as a senior manager for product development, within the R&D department located in Atlanta, Ga.

Strombergsson earned his Master's in mechanical engineering at Chalmers University of Technology in Sweden, and has built on his expertise through programs and classes at various institutions including Emory University and Georgia Tech.

Robert E. Wanerman is a member of the firm in the health care and life sciences practice, in the Washington, DC, office of Epstein Becker Green. His practice concentrates on regulatory, reimbursement and compliance matters affecting health care manufacturers, service providers and investors in health care organizations. He has extensive experience counseling clients in matters arising under the Medicare and Medicaid programs, administrative law and procedure, the False Claims Act, clinical research rules, grant administration rules, the Anti-Kickback and Stark laws, HIPAA and EMTALA.

Mr. Wanerman:

- Advises clients in connection with coverage, coding, and reimbursement for medical technologies under Medicare, Medicaid, and commercial health plans
- Provides counsel on administrative law issues affecting health care manufacturers, suppliers, and providers, and represents clients in administrative hearings and appeals
- Represents clients in government audits, investigations, and litigation arising under the Medicare and Medicaid programs and under the False Claims Act, including negotiating settlements and corporate integrity agreements
- Counsels manufacturers and providers on clinical research contracting and compliance
- Develops and implements compliance programs and policies for medical device and pharmaceutical manufacturers, hospitals, academic medical centers, and long-term care facilities

Mr. Wanerman is a guest lecturer at the Johns Hopkins Carey Business School, Discovery to Market Program. He regularly gives presentations at industry conferences and is consistently ranked by participants as a top speaker.

Outside of the office, Mr. Wanerman is the Vice-President of The Ivymount Foundation, which provides financial support to educational programs for children with developmental delays, speech/language deficits, learning disabilities, health impairments and autism/PDD.

Julie Watson is Special Counsel at Marshall Gerstein & Borun, LLP, a Chicago-based intellectual property law firm. A licensing professional with over 25 years' experience structuring and negotiating complex deals, Ms. Watson concentrates her practice on intellectual property transactions with a particular emphasis in technology startups and university technology transfer. Ms. Watson's prior work includes managing nonprofit intellectual property licensing programs including the Wake Forest Institute for Regenerative Medicine and the American Medical Association. Ms. Watson received her law degree from Wake Forest University Law School and is admitted to practice law in Illinois, North Carolina and before the USPTO. She also holds a master's degree from Johns Hopkins University and is a Certified Licensing Professional.

General Information

AUTM Business Development Course – Medical Devices

AUTM Vice President for Professional Development

Marc Sedam, M.B.A., CLP, *University of New Hampshire*

Program Chair

John Ritter, J.D., M.B.A., *Princeton University*

Program Committee

Alan R. Bentely, *Vanderbilt University*
Pamela L. Cox, J.D., *Marshall, Gerstein & Borun LLP*
J. Craig Fryman, *Zimmer*
Jamie Kemler, *Stryker Corporation*
Vinit Nijhawan, *Boston University*
Ashley Stevens, D.Phil. (Oxon), CLP, *Boston University*

AUTM Business Development Course Is a Paperless Meeting

All registrants will be provided an electronic workbook containing the presentations and will have online access to materials before, during and after the meeting.

Registered Technology Transfer Professional (RTTP)

Demonstrate your expertise in the academic technology transfer profession by becoming a Registered Technology Transfer Professional (RTTP). All AUTM professional development courses and designated educational offerings and meetings are eligible for continuing education (CE) credits, which support your registration application. For more information about the registration process and requirements, visit the Alliance of Technology Transfer Professionals website at www.attp.info.

Certified Licensing Professionals (CLP) Continuing Education

Certified Licensing Professionals are required to demonstrate continued competence in their field to maintain their certification status. Individuals who hold the CLP designation can renew their credential by earning at least 40 continuing education (CE) credits. All AUTM professional development courses and designated educational offerings on the topics of licensing, technology transfer, and technology commercialization at AUTM conferences or meetings are eligible for CLP continuing education (CE) credits for certification renewal. Visit www.licensingcertification.org for more information on the recertification requirements.

The AUTM Business Development course will provide nine hours of continuing education (CE) credits for those who attend the entire meeting.

General Information

AUTM Business Development Course • November 17 – 18, 2015

Hotel

Hyatt Regency Dallas
300 Reunion Boulevard
Dallas, TX 75207 USA
Reservations: +1-888-421-1442
Guest phone: +1-214-651-1234
Fax: +1-214-742-8126

Location

Experience Dallas in the heart of downtown at the Hyatt Regency Dallas. Ascend the 561 foot Reunion Tower, a famous landmark featuring the GeO-Deck observation level and Cloud Nine Café. The hotel is located adjacent to the historic district, West End and entertainment district. You can stay and relax at the hotel's outdoor pool or a workout in the 24 hour gym.

Hotel Accommodations

AUTM has negotiated a discounted rate of $189 for single or double occupancy, plus applicable taxes. These rates will be available to attendees, based on availability, from Saturday, November 14, through Saturday, November 21, 2015. To reserve a room, call the hotel at +1-888-421-1442 and identify yourself as an AUTM meeting attendee to obtain the special rate. **If you prefer, make your reservations online.** Make reservations by October 26, 2015. Discounted room rates may not apply after this date. A credit card guarantee is required to hold your reservation. The hotel will charge the equivalent of one night's room and tax if cancellation notice is not provided to the hotel by noon at least 48 hours before scheduled arrival. Hotel check-in is 3 p.m., and check-out is noon.

Airport Transportation Information

DFW International Airport
The Hyatt Regency Dallas is located about 22 miles from the DFW International Airport. Taxi fare is approximately $45 - $50 each way. There is also the option of using the **Super Shuttle,** which is approximately $17 per person, one way and operates 24 hours a day. Another alternative transportation option is the **DART** (Dallas Area Rapid Transit). The orange line leaves from the airport and goes to the West End station, and guests can take either the red or blue line to get to Union Station (attached to the hotel via underground concourse).

Car Rental

Avis Rent A Car System Inc. is the official car-rental service for the AUTM Business Development Course. Avis agents can provide the best available rates during your stay. For reservations, call +1-800-331-1600 and reference the AUTM Avis Worldwide discount number J867535 to receive special pricing. If you prefer, make your reservation online at **www.avis.com.**

Parking

Reunion Tower
Valet overnight $26 plus taxes with in and out privileges to overnight guests.
Daily guest rates: 0-4 hours $18, 4-8 hours $22 and 8-24 hours $26

Radish Lot
(located on the north end of the hotel at the intersection of Hotel Street and Reunion Boulevard West) In and out privileges for overnight guests only:
Daily guest rate: 0-4 hours $9, 4-8 hours $13, 8+ hours $19

Self-parking is also available in the outdoor Radish Lot – located on the north end of the hotel at the intersection of Hotel Street and Reunion Boulevard West. In and out privileges for overnight guests only. Daily guest rates in the Radish Lot are also available. And lastly the B-Lot, 0-4 hours $6, 4-8 hours $13 and 8+ hours $19.

General Information

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Attire and Weather

Attire for the AUTM Business Development Course is business casual. Dallas' average daytime high temperature in November is 66°F (19°C); the average low temperature is 47°F (8°C).

International Visas

Travelers coming from qualified countries to the United States for tourism or business for 90 days or less may be eligible to visit the United States without a visa. For additional information, visit www.travel.state.gov/visa.

Registration Information

Full meeting registration includes admission to all meeting workshops and group meal functions. **AUTM Member:** Membership in AUTM is on an individual basis and member fees apply only to the individual who is considered a current member in good standing. You do not need to be an AUTM member to attend. AUTM members receive significant member discounts on registration fees.

Processing Registrations

AUTM will process course registrations only when they are accompanied by a check or include credit card information. Please note: Registration forms, with fees paid, must be postmarked (if mailed) or received by fax by September 22, 2015, to qualify for the discounted early rate. Registrations received after September 22 must be paid at the higher rate. To be considered preregistered, your registration, changes or substitutions must be received by November 3, 2015.

Questions

If you have questions about the registration, contact Lauren Rich at AUTM headquarters via email at Lrich@autm.net; by phone at +1-847-559-0846 x352; or fax at +1-847-480-9282.

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AUTM 2015 Business Development Course

November 17 – 18, 2015

Hyatt Regency Dallas • Dallas, TX USA

Register online at: www.autm.net/events
It's fast and secure.

For Office Use:
ID #_____
Reg #_____

Please Print

Complete a separate form for each registrant.

First Name Last Name

❍ Do not post my name on the online pre-registration list.
❍ **Update my member profile with this information.**

Name for badge (if different than above.)

Job Title

Organization

Address

City State/Province Zip/Postal Code

Country

Phone

Email

Emergency Contact Phone

❍ Send a copy of my registration email confirmation to:

Affiliation:

❏ University
❏ Non-Profit Research Institute
❏ Law Firm
❏ Support Industry
❏ Licensing Agent
❏ Accountant
❏ For-Profit Non-Academically Affiliated Research Firm
❏ Teaching Hospital
❏ Academic Research Institute
❏ Government Technology Transfer Program and/or Federal Lab
❏ For-Profit Corporation
❏ Technology Transfer Consultant
❏ Venture Fund
❏ Foundation
❏ Other, please list _____

Please contact AUTM headquarters at +1-847-686-2244; fax: +1-847-686-2253; email: LRich@autm.net, if you have any special needs.

Registration Fees

All fees are quoted in U.S. dollars.
Please check the appropriate fee:

	On or Before Sept. 30	After Sept. 30 and until Nov. 3	After Nov. 3 and in person
AUTM Member*:	❍ $425	❍ $475	❍ $525
Meeting and Membership Package*: (includes an AUTM membership)	❍ $710	❍ $760	❍ $810
Nonmember:	❍ $720	❍ $770	❍ $820

* Membership in AUTM is on an individual basis and member fees apply only to the individual who is a current member in good standing.

Registration Policy:

Attendees who include an email address on their registration form will receive an email confirmation and receipt within 24 hours of registering online. Allow up to five business days if registering by mail or fax. If an email address is not provided, registrants will receive a confirmation in the mail within 14 business days.

Online: Complete online form at www.autm.net/events

Mail: Mail your completed registration form with appropriate payment to:
Association of University Technology Managers
33661 Treasury Center
Chicago, IL 60694-3600 USA

Mailed registrations with payment must be received by **Nov. 3, 2015.** After Nov. 3, all check payments must be processed onsite.

Fax: Fax your completed registration form and credit card information to +1-847-686-2253.

Faxed registrations will only be accepted until **Nov. 3, 2015**. Faxed registrations qualify as paid only when complete credit card information is included. If you fax your registration, do not mail an additional copy.

Cancellation Policy:

Notification of cancellation must be submitted in writing. Cancellations received by **Nov. 3, 2015**, will be subject to a $75 cancellation charge. **No refunds will be given after Nov. 3, 2015.** Substitutions are allowed at any time, but must be submitted in writing and must be of the same membership status.

For U.S. citizens only:

Contributions, gifts, dues or other payments to the Association of University Technology Managers are not deductible for federal income tax purposes as charitable contributions. However, they may be deductible as ordinary and necessary business expenses. Please consult your tax advisor.

* The Meeting and Membership Package includes admission to the 2015 Business Development Course and an AUTM membership, which **will expire December 31, 2015.**

Payment

AUTM Taxpayer ID #36-3011951

❍ Check
Check enclosed for $ _____

Please make check payable to:
Association of University Technology Managers Inc.
Funds must be in U.S. dollars.

❍ Credit Card
❍ VISA ❍ MasterCard ❍ American Express ❍ Discover

Amount $ _____

Print name as it appears on card

Signature

Credit Card Billing Address (if different than above)

City State Zip/Postal Code

Card Number Expiration Date

CAUTION: If you submit your registration form more than once, it may result in a duplicate charge on your credit card.
Please send your registration using only one method of payment and submission.


Annual Meetings

2016
February 14 – 17
Manchester Grand Hyatt San Diego
San Diego, CA USA

2017
March 12 – 15
The Westin Diplomat Resort & Spa
Hollywood, FL USA

2018
February 18 – 21
JW Marriott Desert Ridge Resort & Spa
Phoenix, AZ USA

2019
February 10 – 13
JW Marriott Austin
Austin, TX USA

2020
March 8 – 11
Manchester Grand Hyatt San Diego
San Diego, CA USA

2015 Professional Development

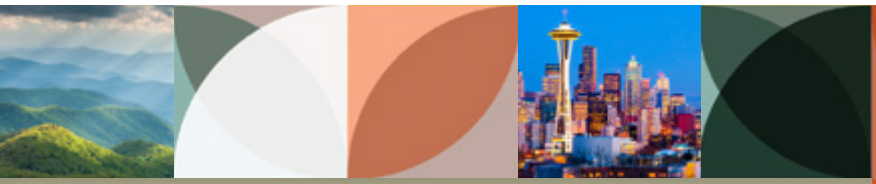
AUTM 2015 Technology Operations and Organization Licensing Skills (TOOLS) Course & Essentials of Academic Technology Transfer
October 5 – 7
The Westin Seattle
Seattle, WA USA

AUTM Business Development Course
November 17 – 18
Hyatt Regency Dallas
Dallas, TX USA

2016 Region Meetings

Central Region Meeting
July 18 – 20
The Pfister Hotel
Milwaukee, WI USA

Eastern Region Meeting
September 29 – 30
The Westin Philadelphia
Philadelphia, PA USA



Save the Date

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