

BOSTON



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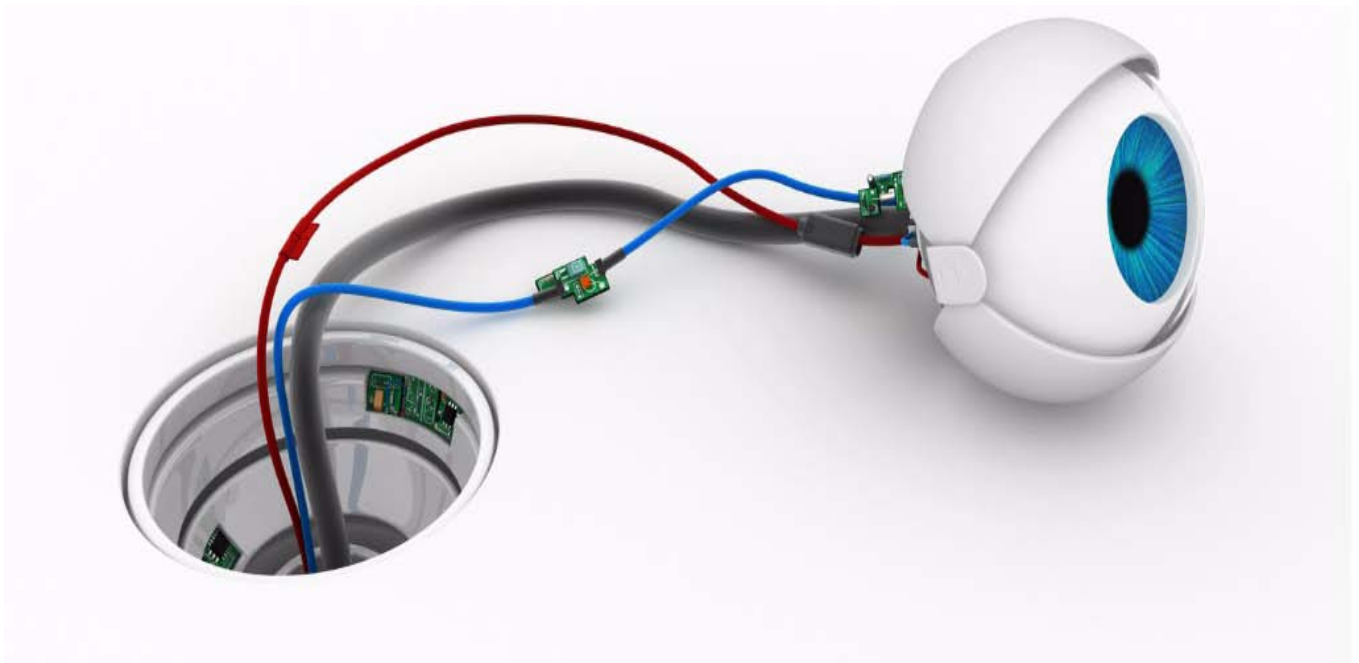


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Rethinking IEEE Chapter Meetings

Paul Zorfass, IEEE Boston Section Chapter Coordinator

The coronavirus pandemic has brought destruction and hardships on many fronts. One of the few positives to have emerged has been the growing acceptance and use of web conferencing platforms that is accompanying the pandemic. These platforms are also beginning to assist us at the IEEE Boston Section to improve information sharing for chapter meetings and increase the location flexibility for attendees.

The web conferencing also lets us introduce the use of the idea of a “Cluster” meeting to describe ways to manage meetings and co-sponsor credits to deliver broader content for the meeting attendees. It also provides chapters to be able to fulfill their IEEE meeting requirements more easily. Co-sponsors for these Cluster meetings will typically be organizations where:

- The products and services of the co-sponsors have similar and compatible technologies that usually works together in the final deliverable product solution
- The engineering solutions and products usually benefit from two or more chapters which combine varied technology solutions
- The roles of co-sponsors and sponsors for the presentations will usually alternate and each will receive meeting credits as presenters or organizers for this meeting

Cluster meetings provide the ability to have wider ranging discussions for technical topics and their implications. Web conferencing extends the ways for attendees to participate in meetings. It permits attendees to overcome additional restrictions imposed by the coronavirus including:

- Ability to log into the meeting from any dispersed, yet

convenient location. This makes work, home, car, public facility, travel destination all suitable entry points for meetings

- Use of attendees’ own computer platforms for connectivity to be assured of end-to-end audio and video reliability
- Multi-task from the preferred location of attendees

The responses to the pandemic accelerated the adoption and use of conferencing and networking solutions. Multiple web conferencing tools increased their marketing efforts. There was no lack of product offerings. Popular ones from larger firms include: GoToMeeting, Hangouts, BlueJeans, Webex, Teams, and Skype. So, it was surprising to me that the early technology winner, ZoomVideo, with its now dominant Zoom product, itself an early-stage company, achieved a commanding lead. This started to become evident at the start of 2020 with the acceleration of the pandemic scourge.

This stable platform (with good synchronization between audio and video) has sufficient software flexibility and functionality, ease of use, all with an attractive price structure. It is comfortable for small as well as large organizations and small organizations within large organizations. Zoom has been able to turn their product name into a verb, as in “let’s zoom later”. These are hard feats to accomplish. And once achieved, very difficult to dislodge. The nature of meetings was changing. Since products in the IEEE technologies markets encounter rapid competitive responses we will watch and be prepared to see how well competitors respond to Zoom.

Many IEEE member companies come from firms with a

long-term corporate commitment to Cisco and its Webex conferencing product line. This product technology has a similar user interface and software functionality to Zoom, making it somewhat straight-forward for IEEE members to utilize either a Zoom or Webex conference platform. The stage is being set for more competition and confrontation at the Web 3.0 level as software platforms compete for organization sales and allegiance.

Currently, we are still in the earlier stages for meetings managed by web conferencing and a cluster view. Yet at the Boston Section we have achieved specific successes to aid in determining the benefits for these organized meetings. With the intersection of the coronavirus and the use of web conferencing, primarily Zoom, and the approach of Clusters we are observing interesting outcomes including:

- For a general audience program on radar's help in winning WW II, we had a dramatic registration increase to approximately 945 individuals. Event attendance was approximately 365 attendees (in contrast to approximately 120 attendees at a similar but not conferenced event). Web conferencing helped make this both a New England meeting and a California meeting. Based on in place communication equipment rather than using Zoom, Webex was the web conferencing platform to carry this meeting.
- For a more technical talk sponsored by the computer society and the reliability society, concerned with rebuilding after Covid-19, there was a very broad geographic response. There were more than 100 attendees with an earlier registration of approximately 300. Since the speaker was from MIT and the talk was advertised on MIT's worldwide PR outlets, the audience

was worldwide in nature with both a large MIT and IEEE presence.

- For another technical meeting where the norm would have been 40 – 50 attendees, mostly IEEE members, here 300 individuals registered and more than 100 attended; there was a large percentage of non-IEEE channels.

- These meetings also demonstrate the potential for using the chapter Cluster meetings as active elements for IEEE membership development efforts. This may require broadening the number of membership categories or other related changes. It also may suggest some changes to membership fees for these newer categories.

- More than meeting attendance measurements has changed. There was also a different dimension to the Q&A period, at the end of the meeting. Attendees appeared to enjoy the mixture of engineering and technology disciplines for the variety and differences of the questions presented.

Even with the positive results there are still concerns that need to get worked out. In particular, we need to better tune how meeting credits are apportioned for fairness to the contribution made by the different co-sponsors. The Clusters have been successfully launched, yet we need to improve the ways that the originating societies are credited and benefit from them and how they are likely to interface between IEEE and non-IEEE modes to yield improvements for chapter meetings and member benefits.

IEEE Boston Section Social Media Links:

Twitter: <https://twitter.com/ieeeboston>

Facebook: <https://www.facebook.com/IEEEBoston>

YouTube: <https://www.youtube.com/user/IEEEBostonSection>

LinkedIn: <https://www.linkedin.com/groups/IEEE-Boston-Section-3763694/about>

IEEE Boston Section Online Courses:

(Students have 180 day access to all online, self-paced courses)

Electronic Reliability Tutorial Series (NEW!!!)

Full course description and registration at ,
<http://ieeeboston.org/electronic-reliability/>

Verilog101:Verilog Foundations

Full course description and registration at ,
<http://ieeeboston.org/verilog-101-verilog-foundations-online-course/>

System Verilog 101: Design Constructs

Full course description and registration at ,
<http://ieeeboston.org/systemverilog-101-sv101-design-constructs-online-course/>

System Verilog 102: Verification Constructs

Full course description and registration at ,
<http://ieeeboston.org/systemverilog-102-sv102-verification-constructs-online-course/>

High Performance Project Management

Full course description and registration at ,
<http://ieeeboston.org/high-performance-project-management-online-course/>

Introduction to Embedded Linux Part I

Full course description and registration at ,
<http://ieeeboston.org/introduction-to-embedded-linux-part-i-el201-online-course/>

Embedded Linux Optimization - Tools and Techniques

Full course description and registration at ,
<http://ieeeboston.org/embedded-linux-optimization-tools-techniques-line-course/>

Embedded Linux Board Support Packages and Device Drivers

Full course description and registration at ,
<http://ieeeboston.org/embedded-linux-bsps-device-drivers-line-course/>

Software Development for Medical Device Manufacturers

Full course description and registration at ,
<http://ieeeboston.org/software-development-medical-device-manufacturers-line-course/>

Fundamental Mathematics Concepts Relating to Electromagnetics

Full course description and registration at ,
<http://ieeeboston.org/fundamental-mathematics-concepts-relating-electromagnetics-line-course/>

Reliability Engineering for the Business World

Full course description and registration at ,
<http://ieeeboston.org/reliability-engineering-business-world-line-course/>

Design Thinking for Today's Technical Work

<http://ieeeboston.org/design-thinking-technical-work-line-course/>

Fundamentals of Real-Time Operating Systems

<http://ieeeboston.org/fundamentals-of-real-time-operating-systems-rt201-on-line-course/>

Artificial Intelligence What's in it for me?

Live, Interactive Webinar Series BEGINNING JAN 2021

The goal of this monthly webinar series is to provide a pulpit to experts in the Artificial Intelligence field to present their expertise and knowledge to other technologists, engineers and scientists.

Confirmed Speakers Include:



Vinton G. Cerf
President & Chief
Internet Evangelist of
Google



Alton D. Romig, Jr.
Executive Officer of the
National Academy of
Engineering



David Cox, IBM
Director of the MIT-
IBM Watson AI Lab



Manuela M. Veloso,
Head of J.P. Morgan
AI Research



Steve Wozniack, Co-
Founder, Apple
Computer



Helen Greiner, Co-
Founder, iRobot

Dates:

Monthly Webinar Series
Next Session:

March 17, 2021

*Featuring Dr. Ken
Washington, Chief
Ford Motor Company*

[**REGISTER NOW!**](#)

Time:

10:30AM – 12:00PM (ET)

Cost:

IEEE Members: \$25.

Non-members: \$35.

Entrepreneur's Network – 7:00PM, Tuesday, February 2

Term Sheets, Negotiations, Contracts & Deal Structure

Location: Webinar

Register: <https://boston-enet.org/event-3892676>
(Please note capacity is limited, so pre-registration is necessary. Registration closes at 3pm on February 2, 2021.)

Company founders getting ready to raise outside financing do not want to give up more equity than absolutely necessary. Investors want more equity for their investment as a reward for the risk they are taking on the young company. Valuation is used to determine a fair trade-off of cash for equity. However, company founders need to consider the following issues:

When do you approach lawyers regarding term sheets?
What is a reasonable valuation for a startup?

Must this determination be made when first obtaining funds?

What terms might an entrepreneur see when presented with a Term Sheet and what are the trade-offs when negotiating these?

How do terms impact founders' managerial control of investments and operating decisions?

Our panel, including two attorneys, a VC, and a serial entrepreneur who has had several successful exits, will discuss these issues concerning valuation and term sheets.

Agenda:

5:30 – 6:45 – Networking on Grapevine Network

7:00 - 7:10 PM - ENET Chairperson's announcements

7:10 - 7:25 PM – eMinute Pitch - Up to 3 Startup companies' presentations

7:25 - 8:10 PM - 4 expert speakers on the night's topic

8:10 - 8:30 PM – Moderator and Audience Q & A with the speakers

8:30 – 9:00 PM - Networking on Grapevine Network
(all times are USA Eastern Daylight time) (all times are USA Eastern Daylight time)

A question and answer session will follow the panel discussion, and panelists will be available afterward for responses to individual questions.

Panelists:



Julie Gionfriddo, Director, Advisory Services FML

Director of Advisory Services for Fiondella, Milone & LaSaracina in Glastonbury, CT. She provides advisory services to funds and companies in the VC and growth capital space. Previously she was a Principal at Apple Tree Partners, a NYC health-care venture capital fund, and just prior to that was a Vice President in the secondary private equity group at Landmark Partners. She is a founding member of the Trinity College Women's Leadership Council, the President of the Women's Association of Venture and Equity, and is a board member of Launc[H] Hartford. She holds both a BA and an MA in Economics from Trinity College.



James Wilkie, CEO of Lowell Therapeutics, Inc.

Jim has 33 years of experience in the life science industry developing both drugs and devices. He is CEO of Lowell Therapeutics, Inc., which is developing products for critically ill patients in the ICU.

Previously Jim was VP of New Enterprise Development at La Jolla Pharmaceutical Company, a publicly traded start up, COO of Pluromed, Inc. until the sale of the company in 2012 to Sanofi, and held various positions of increasing responsibility at MedChem Products, Inc. and co-founded Surgical Sealants, Inc.

Jim holds 4 issued patents, several pending applications and received his B.S. in Engineering from the University of Massachusetts.



Attorney Michael Mahoney, Gesmer Updegrave LLP

Attorney Mahoney holds a B.S. in Anatomy and Cell Biology from McGill University and a J.D. from Boston College Law School. He is an associate at Gesmer Updegrave LLP in Boston, MA and enjoys advising new and emerging companies on a wide variety of corporate matters. Attorney Mahoney regularly counsels start-up companies on choice of entity and equity compensation for employees, directors and consultants. He has also worked with a number of clients on commercial and licensing agreements, equity and debt financings, and mergers & acquisitions.

Attorney Mahoney previously owned two companies and has experience dealing with the day-to-day challenges that face business owners. He enjoys fostering strong relationships with his clients so they feel comfortable reaching out to him to discuss any difficulties that they are facing.



Attorney Justin Nesbit, Gesmer Updegrave LLP

Attorney Nesbit holds a B.A. from Williams College and a J.D. from Boston College Law School. He represents emerging and established companies with many aspects of their legal affairs. Attorney Nesbit enjoys providing advice on complicated legal and business issues and always strives to be a part of his clients' growth and success. In the past he has negotiated and formed numerous licensing, consulting, sales, development and distribution contracts, many on behalf of one of the world's preeminent universities. He has helped to "put together" and close mergers, acquisitions and financings, and he enjoys rolling up his sleeves and working on many aspects of each transaction.

Clients rely on him for a wide variety of advice on the day-to-day corporate matters that every company must address if they wish to build a world-class enterprise. Nothing makes Justin happier than building strong relationships with his clients, whether that involves discussing the search for the perfect college for a client's child or learning about what pressing issues keep the client

up at night.



Attorney Matthew A. Karlyn, Morrison & Foerster LLP

Matthew has a B.A. from Union College, a J.D. from Temple University, and a M.B.A. from the University of Chicago and is authorized to practice law in Massachusetts, Illinois, and New York. He is a partner at the Boston, MA office of Morrison & Foerster LLP. He has 23 years of experience in working with companies in the healthcare, pharmaceutical, medical device, and technology industries on a wide range of commercial life sciences, licensing, and technology transactions. His clients range from Fortune 100 companies to start-ups, and he regularly advises companies on matters involving IP commercialization, complex collaboration transactions, licensing initiatives, subscription-based economics, and business transactions related to the procurement, development, commercialization, and use of technology and life sciences products. He has also worked with a number of clients on corporate transactions including mergers and acquisitions, as well as private equity and venture capital financing.

Life sciences clients, including pharmaceutical, medical device, and healthcare companies, rely on Attorney Karlyn for his breadth of knowledge in licensing, collaboration, and commercialization strategies across a wide range of transactions designed to strengthen operations and maximize value. His clients come from sectors across the global economy and include emerging companies, privately held companies, and many of the world's biggest brands. Matt Karlyn | LinkedIn

Co-Organizers /Moderators



William Mansfield, Secretary Of Boston ENET

Attorney Mansfield is a patent attorney and is a lawyer in MA & NY; high bar exam scores allowed him to waive into the D.C. Circuit. He won the CALI Award for perfect grades in an IP course, and he has passed the Fundamentals of Engineering Exam covering all types of engineering. He assists clients with corporate and intellectual property law using trademarks, trade dress, copyrights, licensing, patents, trade secret protection, strategic partnerships, and succession planning.

From 2004, he has worked on legal matters & he has counseled entrepreneurs/startups since 2009 thru Mansfield Law. He has worked on patent prosecution, especially business method, business process, electrical, mechanical, telecommunications, and e-commerce patents. He has filed for global IP protection and has a network of foreign IP professionals. William A.M. Mansfield, Esq. | LinkedIn



Kristin King, MBA. Vice President, Corporate Development & Strategy, Defibtech, LLC

Kristin is an accomplished MedTech executive, serial intrapreneur, investor and strategic advisor to startups developing biotech solutions. With over 20 years spanning technical, commercial and business skills as well as Boston Harbor Angel Investor, she covers broad expertise transforming technologies from early concept to successful global divisions.

Kristin holds a B.S. in bioengineering from Syracuse



University, MBA in Finance & Marketing from NYU Stern.

Dave Hall, Founder & CEO, DLH Technology, Advisors, Startup Strategy & Venture Capital Consulting

Dave is Founder and CEO of DLH Technology Advisors. He is a startup & strategy Executive, Innovation Consultant, Advisory Board Member, Connector, Evangelist and Speaker for growth companies looking to implement, optimize, and fund their Go-to-Market plan.

DLH Technology Advisors offers consulting services including Startup Strategy, & Frameworks, Business Development, Startup Marketing, Go-to-Market Strategy, Executive Coaching and Startup Funding Channels. DLH has resources for CRM development services including Salesforce implementation, AppExchange App Development, QuickStarts, Lead Architect and Admin Services for the entire Salesforce product line - www.DLHsales.com.

Call for Articles

Now that the Reflector is all electronic, we are expanding the content of the publication. One of the new features we will be adding are technical, professional development, and general interest articles to our members and the local technology community. These will supplement the existing material already in our publication.

Technical submissions should be of reasonable technical depth and include graphics and, if needed, any supporting files. The length is flexible; however, a four to five page limit should be used as a guide. An appropriate guide may be a technical paper in a conference proceeding rather than one in an IEEE journal or transaction.

Professional development or general interest articles should have broad applicability to the engineering community and should not explicitly promote services for which a fee or pay-

ment is required. A maximum length of two to three pages would be best.

To ensure quality, technical submissions will be reviewed by the appropriate technical area(s). Professional/interest articles will be reviewed by the Publications Committee for suitability. The author will be notified of the reviewers' decision.

The Reflector is published the first of each month. The target submission deadline for the articles should be five weeks before the issue date (e.g., June 1st issue date; article submission is April 27). This will allow sufficient time for a thorough review and notification to the author.

We are excited about this new feature and hope you are eager to participate!

Submissions should be sent to;
ieebostonsection@gmail.com

Life Members – 7:00PM, Wednesday, February 10

Brain Wave Therapy: Opportunities and Challenges of Gamma-Inducing Brain Stimulation Interventions in Alzheimer's Disease and Related Dementias

Emiliano Santarnecchi - Berenson-Allen Center for Non-invasive Brain Stimulation, Department of Cognitive Neurology | Beth Israel Deaconess Medical Center | Harvard Medical School | Boston, MA, USA

Location: Webinar

Emiliano Santarnecchi - Berenson-Allen Center for Non-invasive Brain Stimulation, Department of Cognitive Neurology | Beth Israel Deaconess Medical Center | Harvard Medical School | Boston, MA, USA

Thanks to advances in public health and medicine, the life expectancy of the world population continues to lengthen. While longer lifespan is a unique opportunity for society to benefit from the wisdom and experience of the elderly, aging is however also the greatest risk factor for neurodegenerative disorders such as Alzheimer's disease. A fundamental neurobiological substrate of cognitive decline and neurodegeneration appears to involve alteration of neuroinflammatory processes with associated deposition of aberrant proteins in the brain, such as amyloid- β (A β) and phosphorylated tau (p-tau).

Recent pre-clinical work from MIT reveals that induction of fast brain oscillations in the gamma band in mice can modulate activity of microglia, modify inflammatory brain processes, and lead to clearance of A β and p-tau deposition in a mouse model of Alzheimer's disease. Translation of such findings to humans could have transformative impact for patients with Alzheimer's disease and related Dementias, also in light of recent failures of drug-based trials. The presentation will cover recent translational work by Dr. Santarnecchi and his team on the application of noninvasive brain stimulation techniques to induce brain oscillatory activity and protein clearance in patients with Dementia, including

currently undergoing first-in-human clinical trials in Alzheimer's disease and frontotemporal dementia.

Emiliano Santarnecchi is an Assistant Professor of Neurology at Harvard Medical School (Boston, MA, USA), the director of the CME course in "Transcranial Electrical Stimulation (tES) for neuropsychiatric research" at Harvard Medical School, an affiliated Associate Professor at the Department of Physics at Northeastern University (Boston, MA, USA), and the director of the Network Control Laboratory at BIDMC. His main interests lie in the combination of Non-Invasive Brain Stimulation (NIBS), electrophysiology (e.g., EEG, MEG) and neuroimaging (e.g., fMRI, DTI, ASL) to modulate brain activity and measure brain's capacity to respond to external perturbation. He is particularly interested in the development and application of image-guided brain stimulation solutions to increase brain plasticity, modulate connectivity patterns and enhance cognition, with the ultimate goal of developing novel therapeutic options for neurological and psychiatric patients.

His work particularly focuses on the application of oscillatory electrical fields (e.g., transcranial alternating current stimulation - tACS) to induce long-lasting changes in brain oscillations which might translate into therapeutic opportunities for patients with Alzheimer's Disease and other Dementias.

Registration: <https://events.vtools.ieee.org/m/256222>

Photonics Society – 7:00PM, Thursday, February 11

Integrated Optical Phased Arrays: LiDAR, Augmented Reality, and Beyond

Prof. Jelena Notaros, MIT

Location: Webinar



Please Join us on Thursday, February 11th, at 7 pm for the February installment of the 2020-2021 IEEE Photonics Society Boston Chapter's Lecture Series! Prof. Jelena Notaros of MIT will be speaking about Integrated Optical Phased Arrays/

Due to the COVID-19 situation we will be meeting via zoom. Zoom link and registration info (registration is free) will be posted to our website one week before the talk. See below for more details. We hope you can make it!

By enabling optical microsystems with new functionalities, improved system performance, and reduced size, weight, and power, integrated photonics is positioned to enable next-generation optical technologies that facilitate revolutionary advances for numerous fields spanning science and engineering, including computing, sensing, communications, displays, quantum, and biology.

An emerging class of integrated photonic systems is integrated optical phased arrays, which enable manipulation and dynamic control of free-space light in a compact form factor, at low costs, and in a non-mechanical way. As such, integrated optical phased arrays have emerged as a promising technology for many wide-reaching applications, including light detection and ranging (LiDAR) for autonomous vehicles, augmented-reality displays, free-space optical communications, and trapped-ion quantum computing.

This talk will present recent advances in integrated optical phased array architectures, results, and applications. First, the first beam-steering optical phased arrays monolithically integrated with on-chip rare-earth-doped lasers and heterogeneously integrated with CMOS driving electronics will be shown and the first single-chip coherent integrated LiDAR results will be presented; these demonstrations are important steps towards practical commercialization of low-cost and high-performance integrated LiDAR sensors for autonomous vehicles. Next, the first integrated optical phased arrays that focus radiated light to tightly-confined spots in the near field and that generate quasi-Bessel beams will be discussed; these near-field modalities have the po-

tential to advance a number of application areas, such as optical trapping for biological characterization, trapped-ion quantum computing, and laser-based 3D printing. Finally, a novel transparent integrated-phased-array-based holographic display will be proposed as a highly-discreet and fully-holographic solution for the next generation of augmented-reality head-mounted displays; novel passive near-eye displays that generate holograms, the first integrated visible-light liquid-crystal-based modulators, and the first actively-tunable visible-light integrated optical phased arrays will be presented.

Jelena Notaros is an Assistant Professor of Electrical Engineering & Computer Science at the Massachusetts Institute of Technology. She received her Ph.D. and M.S. degrees from the Massachusetts Institute of Technology in 2020 and 2017, respectively, and B.S. degree from the University of Colorado Boulder in 2015. Her research interests are in integrated silicon photonics devices, systems, and applications.

Jelena's work has been published in Nature, OSA, IEEE, and SPIE journals and conference proceedings. She was a Top-Three DARPA Riser, a DARPA D60 Plenary Speaker, a Forbes 30 Under 30 Listee, an MIT Presidential Fellow, a National Science Foundation Graduate Research Fellow, and an MIT EECS Rising Star. Jelena was the recipient of the 2020 MIT RLE Early Career Development Award, 2019 OSA CLEO Chair's Pick Award, 2014 IEEE Region 5 Student Paper Competition Award, 2019 MIT MARC Best Overall Paper Award and Best Pitch Award, 2018 and 2014 OSA Incubic Milton Chang Student Travel Grant, 2014 Sigma Xi Undergraduate Research Award, and 2015 CU Boulder Chancellor's Recognition Award, College of Engineering Outstanding Graduate for Academic Achievement Award, and Electrical Engineering Distinguished Senior Award. She was an invited speaker at 2020 SPIE Photonics West, 2019 OSA CLEO, 2020 OSA FiO, 2019 OSA IPR, 2020 OSA NETWORKS, 2021 OSAAIO, & 2019 IEEE PN.

More info, including registration will be posted shortly at: <http://www.bostonphotonics.org/seminar.aspx?seminar=338>

Entrepreneur's Network – 7:00PM, Tuesday, February 16

Regulatory Compliance. It is Required

Location: Webinar

Register: <https://boston-enet.org/event-3892678>
(Please note capacity is limited, so pre-registration is necessary. Registration closes at 3pm on February 16, 2021.)

Are you concerned with giving away too much equity to finance your start up? Do you know all the start up funding options available?

This panel will focus on getting initial money from non-traditional sources when VCs and angels will not help, and friends and family will stress you out.

Investors want to see something before they invest. Yet it takes money to make your company into something to interest investors. It is a catch-22. This panel offers techniques to show you how to break out of that conundrum - to take your company from nothing to something, and to do so without VC or angel funding. These questions and more will be discussed and answered in this Webinar.

Agenda:

5:30 – 6:45 – Networking on Grapevine Network
7:00 - 7:10 PM - ENET Chairperson's announcements
7:10 - 7:25 PM – eMinute Pitch - Up to 3 Startup companies' presentations
7:25 - 8:10 PM - 4 expert speakers on the night's topic
8:10 - 8:30 PM – Moderator and Audience Q & A with the speakers
8:30 – 9:00 PM - Networking on Grapevine Network
(all times are USA Eastern Daylight time) (all times are USA Eastern Daylight time)

A question and answer session will follow the panel discussion, and panelists will be available afterward for responses to individual questions.

Panel Members

Joanne LaValle, MSHS, RAC, Principal, Regulatory Affairs, Halloran Consulting Group

Joanne LaValle has more than 20 years of experience in regulatory affairs and drug/device development with



a diverse background in regulatory strategy and submissions in small molecules, biologics, vaccines, and medical devices. She has extensive experience in drug/device combination products, pharmacovigilance, compliance, and marketing applications across multiple therapeutic areas including dermatology, oncology, immune-oncology, endocrine, and allergy. She has prepared many types of submissions including IND, BLA, NDA, sNDA, 510(K), PMA, and Special Protocol Assessments. She has actively engaged and led FDA meetings including Pre-IND, EOP, Pre-NDA and Pre-BLA meetings. In addition, she has led multiple FDA drug and device inspections. She has extensive experience with labeling and advertising/promotion regulations and submissions.

Joanne has successfully led the development and post-marketing regulatory activities of drug/device combination products. She has established comprehensive compliance programs and has been responsible for all regulatory related activities including advertising and promotion, cGMP, and the Quality system.

<https://www.linkedin.com/in/joanne-lavalle-mshs-rac-351985105/>



Jeanne Bertonis, Chief Operating Officer, Azitra Inc.

Ms. Bertonis is a seasoned healthcare professional with experience in early stage start-up companies as well as established corporations.

She is currently Chief Operating Officer for Azitra, Inc., a clinical-stage medical dermatology company that leverages extensive scientific knowledge about the skin microbiome to discover and develop novel products for the treatment of adverse skin conditions and diseases. For the past 15 years she has also been providing strategic and business consulting to pharmaceutical, medical device, biomaterial and diagnostic companies. Projects range from the creation of business, product and marketing strat-

egies, to licensing, partnering, and mergers and acquisitions.

She is the past co-founder and CEO of Visgo Therapeutics, which focused on local drug therapies for joint diseases. She was President and CEO of BioSyn-tech, a public biomaterials company with an approved product for cartilage repair, from 2009 to 2010. From 2000-2006, she held the positions of Chief Business Officer and Vice President Corporate Development for Angiotech Pharmaceuticals, the company that developed the paclitaxel-coated stent. Ms. Bertonis has additional experience in business and research positions with Genzyme, Guidant, Eli Lilly and Biogen.

Ms. Bertonis has an MBA from the Kellogg School of Management, an MS from University of Massachusetts, and a BA from Vassar College. She has served as Director for both private and public biotech and device companies.

<https://www.linkedin.com/in/jeanne-bertonis-554803a/>



Geetha Rao, CEO and Founder, Springborne Life Sciences

Dr. Geetha Rao is the founder and CEO of Springborne Life Sciences, a firm based in Silicon Valley providing compliance and strategic advisory services on emerging medical technologies and healthcare innovation. Dr. Rao has worked at the forefront of emerging technologies for her entire career and for over 20 years in the life sciences industry. Her particular focus is on platform technologies with applications in digital health, connected medical systems, and health information and intelligence.

Dr. Rao has worked with numerous start-ups and larger companies. She serves as an advisor at the California Life Sciences Institute, Health Technology Forum, and several other healthcare innovation organizations. She has served as program faculty for the BioDesign

Innovation Program at the Stanford University School of Medicine and as an advisor in several innovation programs the University of California, San Francisco. She has been elected to the Dean's Advisory Council, Physical Sciences Division and Co-Chair of the Innovation Network at University of Chicago and is a member of Chicago Innovation Exchange. Dr. Rao was a contributor on the 2013 World Economic Forum research project on Sustainable Health Systems and a TEDMED scholar. She serves on standards committees for medical technology interoperability and security.

Dr. Rao holds a Ph.D. in Engineering from MIT and a Master's in Business from Stanford University, Graduate School of Business.

<https://www.linkedin.com/in/geetha-rao/>



Moderator, Meeting Organizer

Roger Frechette, Life Science Business Executive / Entrepreneur / Mentor
My daily purpose is to exercise an innate drive to transform ideas and projects into life-changing commercial assets. In the life science business, this is the long game, requiring boundless

energy and creativity, coupled with knowledge, experience, and patience. Consulting services include advisory and fractional executive engagements in operations, strategic planning and business development.

In my work, I leverage an extensive global network and insights derived from >20 years of experience in business development, calibrated with an extensive science background. My career has encompassed success as a business executive, project/alliance manager and entrepreneur, and also as a scientist, including leadership of discovery/preclinical development teams resulting in a new drug candidate – NDAs for omadacycline submitted by Paratek in early 2018.

<https://www.linkedin.com/in/rogerfrechette/>



Electronic Reliability Tutorial Series

(co-hosted by IEEE Boston Section and Ansys Corporation)

Five new, on demand, self-paced courses!

Speakers: Greg Caswell, Dock Brown, Ansys

Series Overview:

Electronics perform critical functions in every major industry vertical, whether in automotive, aerospace, consumer, medical or industrial segments. With the advent of newer technologies (both at the component and material levels), shrinkage of feature sizes, more stringent environments and sophisticated power requirements, electronics face increasing reliability risks. The cost of reliability assurance activities is often a fraction of the cost of failure, with compounding benefits from conducting these activities early in the design process.

This set of five tutorials is aimed at organizations in every industry vertical, who would like to mitigate electronic failures.

Learn how to mitigate electronic reliability risks and prevent failures from industry renowned and award-winning experts.

Benefits of attending the series:

- Understand common failure mechanisms at the electronic component/ package level and the printed circuit board assembly level
- Learn about actionable mitigation methods for relevant failure modes/mechanisms
- How to conduct reliability assessment for electronics
- How to conduct a five-step design activity assurance for electronics
- Electrostatic Discharge (ESD) failures and how to mitigate them
- The Importance of Printed Circuit Board Cleanliness: How to Prevent No Fault Found Failures

Series Tutorial Session Titles

You can view detail session descriptions once you click on the individual sessions once you access the main series website. See the link at the end of the course notice.

1. Thermally Induced Failures and Reliability Risks created by Advancements in Electronic Technologies (2 hours)

2. A Methodology for Understanding the Reliability of Electronic Packaging (2 hours)

3. Electronic Reliability 360: How to Verify Design Robustness Early in the Process (3 hours)

4. Electrostatic Discharge (ESD) for Electronics—What is it? Where Does it Come From? And How do You Obviate ESD Failures? (3 hours)

5. Contamination and Cleanliness Issues in Printed Circuit Board Assemblies (2 hours)

Speaker Bios:

Greg Caswell, a Lead Consulting Engineer for Ansys Corporation, is an industry recognized expert in the fields of SMT, advanced packaging, printed board fabrication, circuit card assembly, and bonding solutions using nanotechnology. He has been well-regarded as a leader in the electronics contract



manufacturing and component packaging industries for the past 50 years. He has presented over 270 papers at conferences all over the world and has taught courses at IMAPS, SMTA and IPC events. He helped design the 1st pick and place system used exclusively for SMT in 1978, edited and co-authored the 1st book on SMT in 1984 for ISHM and built the 1st SMT electronics launched into space. Be on the lookout for his new book entitled Design for Excellence in Electronics

Manufacturing due out in September 2020. Greg has won several awards including the IMAPS Lifetime Achievement Award in 2018, the ISHM Daniel C. Hughes Award (highest award given to an individual), ISHM Fellow of the Society Award and the Tracor Technical Innovation Award.



Dock Brown brings his more than 30 years of electronics reliability experience to clients of Ansys. Prior to joining Ansys, he spent 20 years at Medtronic where he most recently concentrated on cross business unit implementation of reliability initiatives for Class III medical devices. He was also responsible for supplier assessment and approval, on-going supplier audits, failure analysis, corrective actions, MRB, sampling, and ultimately full accountability for quality and reliability of COTS and custom parts and assemblies from a worldwide supplier base. Earlier in his career, Mr. Brown also spent time at Sundstrand Data Control where he led the implementation of the Boeing AQS program and with Olin Aerospace.

As a volunteer, he has been involved with ASQ, IEEE, IPC, and SMTA. He was the keynote speaker at the SMTA Cleaning Conference. He has taught design for reliability, tin whiskers, statistics, design of experiments, and contributed to standards development. He has won the SMTA Distinguished Speaker award and the SMTA Microelectronics Conference Best Paper award.

Individual tutorial/session abstract, goals, benefits of attending, target audience can be found by clicking on the title of each tutorial/session once the main series site is accessed (see below)

Each tutorial is listed separately in the course catalog on our on demand course platform “myicourse” and each tutorial is a separate registration.

REGISTER NOW!

2 hour tutorials - \$70 each

3 hour tutorials - \$105 each

Introduction to Practical Neural Networks and Deep Learning (Part I)

Times and Dates : 9:00AM - 12:15PM, Saturday, March 20, 2021
(3 hours of instructions!)

Speaker: CL Kim

Location: A live, interactive webinar

Overview:

From the book introduction: "Neural networks and deep learning currently provides the best solutions to many problems in image recognition, speech recognition, and natural language processing."

This Part 1 and the planned Part 2 (late spring/early summer 2021, to be confirmed) series of courses will teach many of the core concepts behind neural networks and deep learning.

Reference book:

"Neural Networks and Deep Learning" by Michael Nielsen, <http://neuralnetworksanddeeplearning.com>

More from the book introduction: "We'll learn the core principles behind neural networks and deep learning by attacking a concrete problem: the problem of teaching a computer to recognize handwritten digits. ...it can be solved pretty well using a simple neural network, with just a few tens of lines of code, and no special libraries." "But you don't need to be a professional programmer." The code provided is in Python, which even if you don't program in Python, should be easy to understand with just a little effort.

Benefits of attending the series:

- * Learn the core principles behind neural networks and deep learning.
- * See a simple python program that solves a concrete problem: teaching a computer to recognize a handwritten digit.

- * Improve the result through incorporating more and more of core ideas about neural networks and deep learning.
- * Principle-oriented, with worked-out proofs of fundamental equations of backpropagation for those interested.
- * Yet hands-on practical, with simple code examples.

Course Background and Content:

This is a live instructor-led introductory course on Neural Networks and Deep Learning. It is planned to be a two-part series of courses. The first course is complete by itself. It will be a pre-requisite for the planned second course. The class material is mostly from the highly-regarded and free online book "Neural Networks and Deep Learning" by Michael Nielsen, plus additional material such as some proofs of fundamental equations not provided in the book, and (in planned Part 2) touching on more recent neural network types such as ResNet.

Agenda

Introduction to Practical Neural Networks and Deep Learning (Part 1)

Feedforward Neural Networks.

- * Simple (Python) Network to classify a handwritten digit
- * Learning with Gradient Descent
- * How the backpropagation algorithm works
- * Improving the way neural networks learn:
- ** Cross-entropy cost function

** Softmax activation function and log-likelihood cost function
 ** Rectified Linear Unit
 ** Overfitting and Regularization:
 *** L2 regularization
 *** Dropout
 *** Artificially expanding data set
 *** Hyper-parameters

Introduction to Practical Neural Networks and Deep Learning (planned Part 2, to be confirmed)
 Convolutional Neural Networks.

* Local receptive field, Feature map. * Pooling layer. * Simple (Python) Convolutional Neural Network to classify a handwritten digit. * Improving the network, Regularization. * Touch on more recent progress in image recognition, such as Residual Network (ResNet).

Pre-requisites:

There is some heavier mathematics in proving the four fundamental equations behind backpropagation, so a ba-

sic familiarity with multivariable calculus and linear algebra is expected, but nothing advanced is required. (The backpropagation equations can be also just accepted without bothering with the proofs since the provided python code for the simple network just makes use of the equations.)

Speaker Background:

CL Kim works in Software Engineering at CarGurus, Inc. He has graduate degrees in Business Administration and in Computer and Information Science from the University of Pennsylvania. He has previously taught for a few years the well-rated IEEE Boston Section class on introduction to the Android platform and API.

**Decision (Run/Cancel) Date for this Course is
Monday, March 15**

IEEE Members	\$110
Non-members	\$130

http://ieeeboston.org/event/neuralnetworks/?instance_id=2987

Call for Course Speakers/Organizers

IEEE's core purpose is to foster technological innovation and excellence for the benefit of humanity. The IEEE Boston Section, its dedicated volunteers, and over 8,500 members are committed to fulfilling this core purpose to the local technology community through chapter meetings, conferences, continuing education short courses, and professional and educational activities.

Twice each year a committee of local IEEE volunteers meet to consider course topics for its continuing education program. This committee is comprised of practicing engineers in various technical disciplines. In an effort to expand these course topics for our members and the local technical community at large, the committee is publicizing this CALL FOR COURSE SPEAKERS AND ORGANIZERS.

The Boston Section is one of the largest and most technically diverse sections of the IEEE. We have over 20 active chapters and affinity groups. If you have an expertise that you feel might be of

interest to our members, please submit that to our online course proposal form on the section's website (www.ieeeboston.org) and click on the course proposal link (direct course proposal form link is

<http://ieeeboston.org/course-proposals/>. Alternatively, you may contact the IEEE Boston Section office at ieeebostonsection@gmail.com or 781 245 5405.

- **Honoraria can be considered for course lecturers**
- Applications oriented, practical focused courses are best (all courses should help attendees expand their knowledge based and help them do their job better after completing a course)
- Courses should be no more than 2 full days, or 18 hours for a multi-evening course
- Your course will be publicized to over 10,000 local engineers
- You will be providing a valuable service to your profession
- Previous lecturers include: Dr. Eli Brookner, Dr. Steven Best, Colin Brench, to name a few.

Python Applications for Digital Design and Signal Processing

Times and Dates (for live Q&A sessions) : 7 - 8PM ET, February 4, 11, 18, 25, 2021

Speaker: Dan Boschen

(Last Notice before Course Begins, Please Register Now!!!)

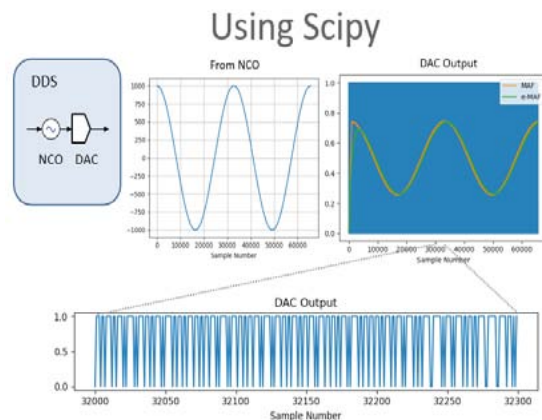
This is a hands-on course combining pre-recorded lectures with live Q&A and workshop sessions in the popular and powerful open source Python programming language.

New Format with Pre-Recorded Videos: The course format has been updated to release pre-recorded video lectures that students can watch on their own schedule, and an unlimited number of times, prior to live Q&A workshop sessions on Zoom with the instructor. The videos will also be available to the students for viewing for up to two months after the conclusion of the course.

Overview: Dan provides simple, straight-forward navigation through the multiple configurations and options, providing a best-practices approach for quickly getting up to speed using Python for modelling and analysis for applications in signal processing and digital design verification. Students will be using the Anaconda distribution,

which combines Python with the most popular data science applications, and Jupyter Notebooks for a rich, interactive experience.

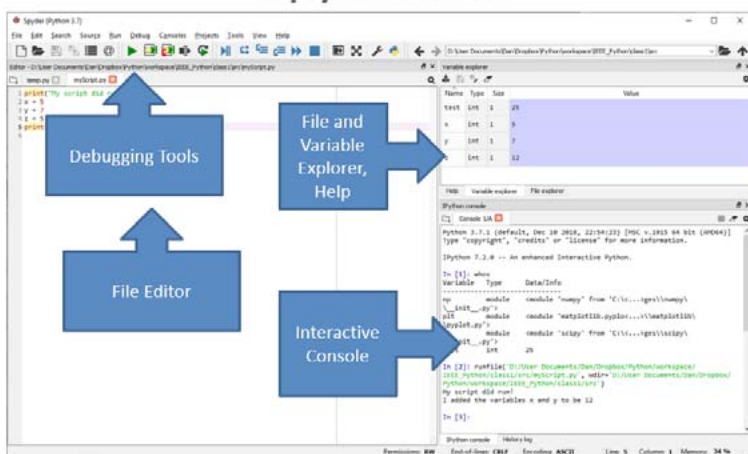
The course begins with basic Python data structures and constructs, including key "Pythonic" concepts, followed by an overview and use of popular packages for scientific computing enabling rapid prototyping for system design.

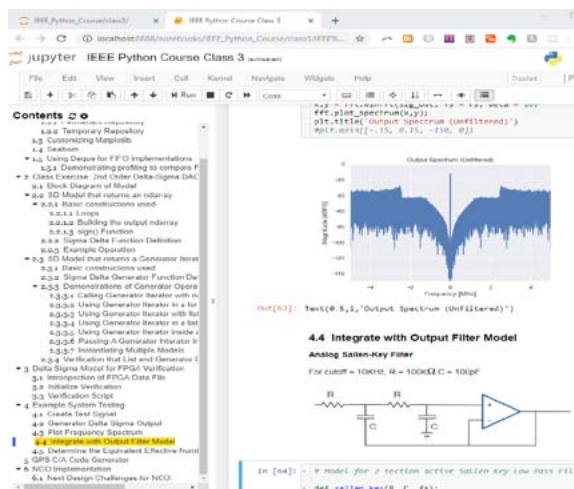


During the course students will create example designs including a sigma delta converter and direct digital synthesizer both in floating point and fixed point. This will include considerations for cycle and bit accurate models useful for digital design verification (FPGA/ASIC), while bringing forward the signal processing tools for frequency and time domain analysis.

Jupyter Notebooks: This course makes extensive use of Jupyter Notebooks which combines running Python code with interactive plots and graphics for a rich user experience. Jupyter Notebooks is an open-source web-based application (that can be run locally) that allows users to create and share visually appealing documents containing code, graphics, visualizations and in-

Spyder IDE





interactive plots. Students will be able to interact with the notebook contents and use “take-it-with-you” results for future applications in signal processing.

analysis and design.

A laptop (Mac or PC) preconfigured with Anaconda is required; the specific installation instructions will be emailed to students prior to the start of class.

Pre-recorded lectures (3 hours each) will be distributed Friday prior to all Workshop dates. Workshop/Q&A Sessions are 7pm-8pm on the dates listed below:

OUTLINE

Thursday, February 4

Topic 1: Intro to Jupyter Notebooks, the Spyder IDE and the course design examples. Core Python constructs.

Thursday, February 11

Topic 2: Core Python constructs; iterators, functions, reading writing data files.

Thursday, February 18

Topic 3: Signal processing simulation with popular packages including NumPy, SciPy, and Matplotlib.

Thursday, February 25

Topic 4: Bit/cycle accurate modelling and analysis using the design examples and simulation packages

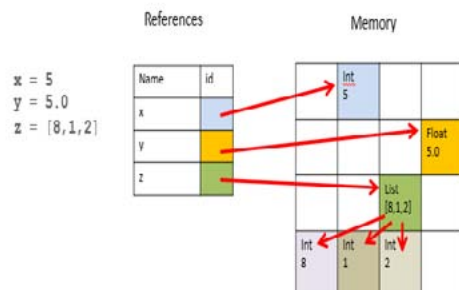
Biography:

Dan Boschen has a MS in Communications and Signal Processing from Northeastern University, with over 25 years of experience in system and hardware design for radio transceivers and modems. He has held various positions at Signal Technologies, MITRE, Airvana and Hittite Microwave designing and developing transceiver hardware from baseband to antenna for wireless communications systems. Dan is currently at Microchip (formerly Microsemi and Symmetricom) leading design efforts for advanced frequency and time solutions. For more background information, please view Dan's Linked-In page

IEEE Members \$190
Non-members \$210

Target Audience: This course is targeted toward users with little to no prior experience in Python, however familiarity with other modern programming languages and an exposure to object-oriented constructs is very helpful. Students should be comfortable with basic signal processing concepts in the frequency and time

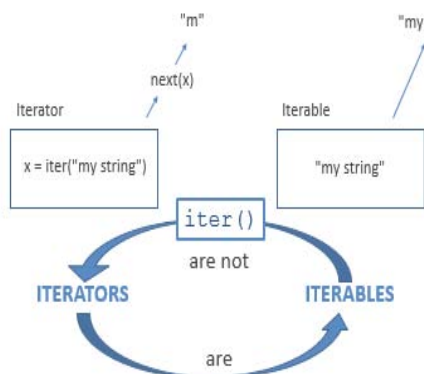
Mutable / Immutable



domain. Familiarity with Matlab or Octave is not required, but the equivalent operations in Python using the NumPy package will be provided for those students that do currently use Matlab and/or Octave for signal processing applications.

Benefits of Attending / Goals of Course: Attendees will gain an overall appreciation of using Python and quickly get up to speed in best practice use of Python and related tools specific to modeling and simulation for signal processing

Iterable and Iterator



Modern Applications of RISC-V CPU Design

Access Period: March 1 - 31, 2021

Speaker: Steve Hoover, Redwood, EDA

Type of Course: Self-paced, on-demand Course. Lab format

Course Overview: CPUs are a fundamental building block of complex SoCs, and RISC-V is taking hold as the ISA of choice. In this workshop, you will create a Verilog RISC-V CPU from scratch, and you will modify this CPU to be suitable for different applications.

You will learn and use modern techniques, using Transaction-Level Verilog to generate and modify your Verilog code more reliably, in far less time. You will discover how concepts like pipelining and hazards can be incorporated easily using timing-abstract design principles. All labs will be completed online in the Makerchip.com IDE for open-source circuit design. The skills you learn will be applicable far beyond CPU design.

Outline of Topics to be Covered:

Digital logic using TL-Verilog and Makerchip

- combinational logic
- sequential logic
- pipelined logic
- validity
- a calculator circuit

Basic RISC-V CPU microarchitecture

- single-cycle CPU microarchitecture
- testbench, test program, and lab setup for your CPU
- fetch, decode, and execute logic for RISC-V subset
- control flow logic

Pipelined RISC-V subset CPU microarchitecture

- simple pipelining of the CPU
- hazards and PC redirects

Completing the RISC-V CPU

- data memory and load/store
- remaining RISC-V (RV32I) instructions

Course Format:

- self paced, on demand course, providing attendees a flexible schedule

- access to content for 30 days
- pre-scheduled live Zoom and chat sessions with the instructors during the 30 day access period
- offline chat available with instructors during the entire 30 day access period (reply within 24 hours).

Target Audience: Engineers interested in a career in digital logic design or adjacent disciplines, including experienced engineers looking to modernize their skill set.

Prerequisites: An engineering education and basic understanding of digital logic. (Verilog knowledge is not a prerequisite.)

Benefits of Attending:

- Develop a solidified understanding of pipelined CPU design through hands-on labs.
- Acquire knowledge of advanced digital circuit design methodology.
- Gain exposure to an open-source design ecosystem.

Speaker Bio: Steve Hoover is the founder of Redwood EDA, an early-stage startup focused on advanced silicon design methodology and tools. Steve is a former logic design lead for DEC, Compaq, and Intel and has extensive experience designing high-performance server CPUs and network switches.

System Requirements: All resources are free and online; no download or installation required. We will use Slack, Zoom, GitHub Classroom, and Makerchip.com.

Decision (Run/Cancel) Date for this Course is Thursday, February, 25, 2021

IEEE Members	\$350
Non-members	\$395

http://ieeeboston.org/event/modern-applications-of-risc-v-cpu-design-course/?instance_id=2955

Polar Codes - Encoding and Decoding Aspects

Web-based Course with live Instructor!

Times & Dates: 10AM ET, Tuesdays, March 2, 9, 16, 23, Thursdays, March 4, 11, 18, 25, 2021

Speaker: Orhan Gazi, Cankaya University, Ankara-Turkey

Course Format: Live Webinar, 8 one hour, sessions

Overview: Forward error correction is a vital process in communication systems. **The last channel codes discovered in the research world are the "polar codes" which are adapted to be used in 5G standard.** The construction and decoding of polar codes are quite different from the construction and decoding of classical channel codes. Polar codes are the only codes constructed in a non-trivial manner. The discovery of polar codes can be considered as a breakthrough in coding society. It is clear that future channel codes will follow the logic of polar codes. For this reason, it is critical to learn the encoding and decoding philosophy of the polar codes which is the state of art of the coding world.

Outline of the topics to be covered:

- Entropy and Mutual Information
- Philosophy of Polar Codes
- Generator Matrices of Polar Codes
- Polar Encoder Structures
- Recursive Structures for Polar Encoders
- Channel Splitting and Concept of Channel Polarization
- Split Channels
- Calculation of Split Channel Capacities
- Polar Decoding
- Polar Decoding for Noiseless Transmission
- Polar Decoding Formulas for Kernel Structure for noisy Transmission
- Successive Cancellation Decoding of Polar Codes
- Polar Encoders and Decoders in 5G New Radio (NR) and Future Channel Codes

Target Audience: Electronic and Communication Engineers, electronic engineers, computer engineers, engineers working in communication industry

Benefits of Attending Course:

- 1) The participant will have an idea about the state of art polar codes.

- 2) Polar codes are used in 5G standard; the participant can comprehend the polar code used in 5G standard.

- 3) The participant will learn successive cancellation decoding of polar codes.

Speaker Bio: Prof. Orhan Gazi is the author of the book "Polar Codes. A Non-Trivial Approach to Channel Coding" which can be reached from <https://www.springer.com/gp/book/9789811307362> The book is selected by IEEE COMSOC as one of the best readings in polar codes, <https://www.comsoc.org/publications/best-readings/polar-coding>

Prof. Orhan Gazi is the sole author of 10 books written in electrical engineering subjects. Apart from the polar code book, he is the single author of the books "Information Theory for Electrical Engineers"

<https://www.springer.com/gp/book/9789811084317> and "Forward Error Correction via Channel Coding"

<https://www.springer.com/gp/book/9783030333799>. The research area of Prof. Orhan Gazi involves "channel coding", and "digital communication subjects". Recently, he focuses on over capacity data transmission using polar codes. He is also interested in practical applications of communication systems involving FPGA devices. He is delivering courses with titles "VHDL circuit design", "interface design using VHDL for FPGA devices" and "system on chip design".

Materials to be included: Lecture slides will be provided.

Decision (Run/Cancel) Date for this Course is Tuesday, February, 23, 2021

IEEE Members	\$250
Non-members	\$300

http://ieeeboston.org/event/polar-codes-encoding-and-decoding-aspects-live-webinar/?instance_id=2965

Software Development for Medical Device Manufacturers

Web-based Course with live Instructor!

(11 hours of instructions!)

Times & Dates: 1:00 - 4:00PM ET, May 3, 4, 5, 6, 2021

Speaker: Steve Rakitin, Software Quality Consulting

Course Format: Live Webinar, four, 3 hour sessions

COURSE SUMMARY: Developing software in compliance with the FDA Design Control regulation, changing FDA guidance documents and latest international standards is challenging. This intensive course provides practical solutions and suggestions for developing software in a manner that meets applicable FDA regulations, guidance documents and international standards, such as IEC-62304:2015. The focus is on interpreting Design Controls for software. Each section of the Design Controls regulation (820.30) is discussed from the perspective of software development. Discussions on key topics such as Software Requirements, Traceability, Design Reviews, Software Verification & Validation and Risk Management (including recently updated standards ISO-14971:2019 and EN-14971:2019) are included. Also discussed are FDA requirements for validation of software development tools and software used in Manufacturing and Quality Systems. Also discussed are recent FDA Guidance Documents on Cybersecurity, Mobile Apps, and Usability.

THIS COURSE IS INTENDED FOR: Software engineers, project managers, quality managers, software quality professionals, RA/QA staff, and anyone who needs to develop cost-effective processes and procedures that will enable their organizations to deliver high quality software-based medical devices that comply with FDA regulations and international standards. This course is also appropriate for people who are new to the medical device industry. Course notes, access to an extensive collection of reference documents and a training certificate are provided.

COURSE OUTLINE: This course will be presented with a live instructor using web-meeting software. The course content will be covered in 4 sessions as described below.

SESSION 1 – Regulatory Context

Duration ~3 hours with one 15 min break

This session will cover key regulatory requirements for medical device software in the US and EU.

Regulations and Guidance:

- FDA Medical Device Regulation (21 CFR Part 820 – specifically, design controls)
- EU Medical Device Regulation
- FDA Guidance Documents:
 - Guidance for Content of Pre-market Submissions for Medical Devices Containing Software
 - Off-the-Shelf Software Use in Medical Devices
 - General Principles of Software Validation
 - Content of Premarket Submissions for Management of Cybersecurity in Medical Devices
 - Policy for Software Device Functions and Mobile Medical Applications
 - Applying Human Factors and Usability Engineering to Medical Devices

International Standards:

- ISO 13485:2016 Medical Devices – Quality Management Systems
- IEC 62304: 2015 Medical Device Software – Software Lifecycle Processes
- ISO 14971: 2019 Application of Risk Management to Medical Devices

- EN 14971: 2019 Application of Risk Management to Medical Devices
- Off-the-Shelf (OTS) Software and Open Source software (SOUP)
- Discussion: All Software Is Defective...

SESSION 2 – FDA Design Controls and IEC 62304 – Part 1

Duration ~2.5 hours with one 15 min break

This session will cover FDA Design Controls and IEC 62304 requirements for medical device software.

- Design and Development Planning
 - How does Agile Development fit?
 - Medical Device Software Lifecycle Processes
- Risk Management
 - FDA Levels of Concern
 - IEC 62304 Software Safety Classification
- Software Requirements
 - Techniques for Removing Ambiguity from Requirements
- Software Architecture and Design
- Software Design Changes

SESSION 3 – FDA Design Controls and IEC 62304 – Part 2

Duration ~2.5 hours with one 15 min break

This session will cover Software Verification and Validation requirements.

- Software Implementation
- Software Verification
 - Technical Reviews
 - Static Analysis
 - Unit and Integration Testing
- System Testing
- Software Validation Testing

SESSION 4 – Software Tool Validation and Risk Management

Duration ~2.5 hours with one 15 min break

This session will cover Software Tool Validation and Risk Management requirements.

- Software Tool Validation

- Deciding which tools need to be validated
- Validation approach for software tools
- Validation of Manufacturing Software and Quality System Software
- Risk Management Using Fault Tree Analysis (FTA)
 - Review of ISO/EN 14971:2019 Requirements
 - Example of Fault Tree Analysis and Failure Modes Effect Criticality Analysis (FMECA)

About the instructor: Steven R. Rakitin has over 45 years experience as a software engineer. He has over 30 years of experience in the medical device industry and has been a medical device consultant for over 20 years. He has worked with over 100 medical device manufacturers and biotech companies worldwide, from startups to Fortune 100 corporations. He has published papers on medical device software risk management as well as a book titled: Software Verification & Validation for Practitioners and Managers.

He received a BSEE from Northeastern University and an MSCS from Rensselaer Polytechnic Institute. He earned certifications from the American Society for Quality (ASQ) as a Software Quality Engineer (CSQE) and Quality Auditor (CQA). He is a Senior Life member of IEEE.

Steve works collaboratively with medical device companies to help them comply with FDA regulations, guidance documents, and international standards in an efficient and cost-effective manner.

**Decision (Run/Cancel) Date for this Course is
Monday, April 26, 2021**

IEEE Members	\$285
Non-members	\$345

Call for Articles

Now that the Reflector is all electronic, we are expanding the content of the publication. One of the new features we will be adding are technical, professional development, and general interest articles to our members and the local technology community. These will supplement the existing material already in our publication.

Technical submissions should be of reasonable technical depth and include graphics and, if needed, any supporting files. The length is flexible; however, a four to five page limit should be used as a guide. An appropriate guide may be a technical paper in a conference proceeding rather than one in an IEEE journal or transaction.

Professional development or general interest articles should have broad applicability to the engineering community and should not explicitly promote services for which a fee or payment is

required. A maximum length of two to three pages would be best.

To ensure quality, technical submissions will be reviewed by the appropriate technical area(s). Professional/interest articles will be reviewed by the Publications Committee for suitability. The author will be notified of the reviewers' decision.

The Reflector is published the first of each month. The target submission deadline for the articles should be five weeks before the issue date (e.g., June 1st issue date; article submission is April 27). This will allow sufficient time for a thorough review and notification to the author.

We are excited about this new feature and hope you are eager to participate!

Submissions should be sent to;
ieeebostonsection@gmail.com

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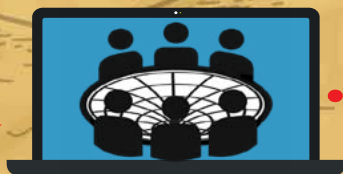


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VIRTUAL PANEL SESSION

Meeting the Device and Test Challenges of Wi-Fi 6E

February 23

11am ET



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A Note from the HPEC Committee:

IEEE HPEC 2021 will be presented as a virtual conference that will allow safe participation and full publication in IEEE Xplore.

The IEEE High Performance Extreme Computing Conference (HPEC '21) will be held in the Greater Boston Area, Massachusetts, USA on 21 – 23 September 2021. The HPEC charter is to be the premier conference in the world on the confluence of HPC and Embedded Computing.

The technical committee seeks new presentations that clearly describe advances in high performance extreme computing technologies, emphasizing one or more of the following topics:

- AI / Machine Learning
- Graph Analytics & Network Science
- Advanced Multicore Software Technologies
- Advanced Processor Architectures
- Automated Design Tools
- Big Data & Distributed Computing
- Big Data Meets Big Compute
- Case Studies & Benchmarking of Applications
- Cloud HPEC
- Computing Technologies for Challenging Form Factors
- ASIC & FPGA Advances
- Quantum and Non-Deterministic Computing
- Data Intensive Computing
- Digital Front Ends
- Fault-Tolerant Computing
- Embedded Cloud Computing
- General Purpose GPU Computing
- High Performance Data Analysis
- Interactive and Real-Time Supercomputing
- Mapping & Scheduling of Parallel & Real-Time Applications
- New Application Frontiers
- Open System Architectures
- Cyber Analysis and Secure Computing

HPEC accepts two types of submissions:

1. Full papers (up to 6 pages, references not included; additional pages can be purchased for \$200/page).
2. Extended abstracts (up to 2 pages, references included).

IMPORTANT DATES:

Submission Deadline: **JUL 9, 2021**
 Notification of Acceptance: **AUG 13, 2021**
 Camera Ready Deadline: **AUG 31, 2021**

Preference will be given to papers with strong, quantitative results, demonstrating novel approaches or describing high quality prototypes. Authors of full papers can mark their preference for a poster display or an oral presentation. Presenters who wish to have hardware demonstrations are encouraged to mark their preference for a poster display. Accepted extended abstracts will be displayed as posters. Papers can be declared "student paper" if the first author was a student when doing the presented work, and will be eligible for the "IEEE HPEC Best Student Paper Award." Papers should not be anonymized. All paper and extended abstract submissions need to use the approved IEEE templates. Full paper submissions with the highest peer review ratings will be published by IEEE in the official HPEC proceedings available on IEEE eXplore. All other accepted submissions and extended abstracts are published on ieee-hpec.org.

Vendors are encouraged to sign up for vendor booths. This will allow vendors to present their HPEC technologies in an interactive atmosphere suitable for product demonstration and promotion. We welcome input (hpec@ieee-hpec.org) on tutorials, invited talks, special sessions, peer reviewed presentations, and vendor demos. Instructions for submitting will be posted on the conference web site shortly.

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