EPIC Members Event Report

STRATEGIES IN Biophotonics™

BOSTON PARK PLAZA HOTEL
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www.strategiesinbiophotonics.com

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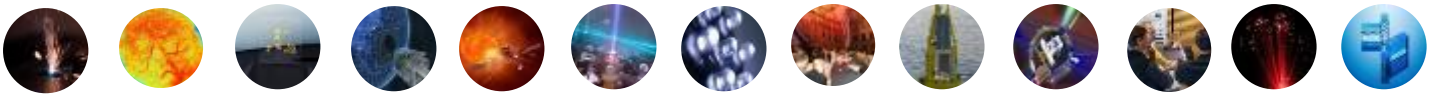
About the EPIC Members Event Reports

Initiated by the founder of EPIC Dr. Thomas Pearsall in 2003, these reports are prepared by members of EPIC to the benefit of the wider community. If you did not have a chance to attend the event but would like to know some key highlight, this report is for you. Emphasis is placed on exploring technical and business opportunities for the members of EPIC.



Strategies in BioPhotonics was dedicated to enabling product development and market success for Biophotonics technologies. The advisory board and program committee are led by **Barbara Goode**, Editor-in-Chief of Bio Optics World, and **Conard Holton**, Editor-in-Chief of Laser Focus World. The event (two and half days) was structured around keynote sessions given by leaders in development and commercialization of photonics-based medical products, specific and key issues conferences to product development and commercialization and round tables. The goal was to deliver insights and advices designed to help Biophotonics-based system developers and entrepreneurs. An exhibition took place with around 40 booths, and some demos took place during coffee break and free times. It was first edition of this event. Total attendance was 480; there were around 60 attendees in the conference hall at any one time, near quasi-exclusively coming from USA and Canada and a few from Europe and Asia.

DAY 1 PRESENTATIONS SUMMARY

Robert S. Langer, a professor at the MIT, (Cambridge, MA) spoke on creating and implementing breakthrough technologies; Langer holds patents that have been licensed by more than 250 pharmaceutical, chemical, biotechnology, and medical-device companies. He explained several different case studies in the areas of drug delivery, medical devices, and biotherapeutics, examining them in terms of the process and excitement of discovery, any initial resistance by the scientific community, patenting, the technology transfer to companies, and their commercialization.

Dr Anita Goel (Chairman and CEO of Nanobiosym gave a talk about “Shedding light on nano-machines that read & write DNA”. She explained how advanced nanotech probe and precision control biological nano-machines used to read and write DNA. These nano-machines have a huge potential for the next generation of nano-sensors for pathogen detection. She compared the different cost, time and feature of the HIV tests (300 million per year). She concluded with the different industrial applications of this multibillion market as medical, bio defense, bio pharma, agriculture and bio fuels, water testing and food and beverage safety.

Robert Nordstrom, Program Director of the Cancer Imaging Program at the National Cancer Institute has developed during his talk some concepts about “Translating Biophotonics ideas to commercial utility : the long journey”. Mains opportunities in Biophotonics are: cancer treatment and diagnosis, neuroscience (optogenetics, connectome, Brain initiative…), infectious diseases and drug development and delivery. The translational research (“bench to bedside”) has a long cycle (10 to 15 years) and Quality Management is the vehicle used to do it and it is required by FDA to ensure safety and efficacy. There are 2 ways: Hand-off to industry and business start-up. The recommendations of R. Nordstrom are : Reduced the knowledge gap between Biophotonics science and clinical users, establish academic entrepreneurial centers to disseminate translational research information, encourage the use of Quality Management in academic laboratories, engage the professional societies to promote the use of standards (ISO, ANSI…) and Quality Management in all aspects of Biophotonics research.

Joseph Schmitt, PhD, Vice president of advanced technologies, St Jude Medical, expounded the success story of intravascular OCT from the Lightlab Imaging start-up (MIT Licenses, funding from Carl Zeiss and NIH, 1998) to the acquisition by Jude (2010, 80 employees) to the dedicated subsidiary of St Jude (2014, +250 employees). He described the non text book approach path of the MedTech start-up: Invent novel technology, explore medical applications, build many prototypes, and try to sell to medical devices or pharma company. Facing to the blood opacity to OCT, there were 5 systems during the 10 years of product evolution. J.Schmidt gave us some hard earned advices: Work in both directions iteratively: clinical needs identification and technology development; Deal with your Achilles’ heel early, don’t hide from it or minimize it; Focus on cost/benefit and clinical outcome, design for usability, quality, and manufacturability.

Eric Buckland, PhD, Co-founder and CEO Bioptigen, gave a talk about "Navigating the competitive world of ophthalmic OCT". He explained the success of Bioptigen to develop and sell a sustainably differentiated OCT platform, by the combination of early sales, angel financing, SBIR grants (approaching $10M, 25 - 30% of development spend over 7 years) and strategic partnership. They create pediatric OCT market with handheld devices and they worked for adoption of OCT image-guided ophthalmic surgery. The Buckland's recommendations are: Developing great technology, nurturing great partnership, identifying unmet needs, securing capital and building a great team.

A group of talks under the heading Biophotonics Tools aimed to address how optics and photonics components can affect product development. It included "Disposable optics for biomedicine" by Randal Chinnock, CEO, Optimum Technologies; "How technology advances are changing scientific imaging," by Stephanie Fullerton PhD of Hamamatsu's Camera Products Group; "The promise of compact supercontinuum for biomedicine" by Philippe Leproux, Associate Professor, Photonics, Institut de Recherche XLIM; and "Specifying filters for biophotonics applications" by Amber Czajkowski, Thin Films Engineer with Edmund Optics.

DAY 2 PRESENTATIONS SUMMARY

Greg Olsen, PhD, President GHO ventures, based on his personal and various experiences (research scientist, entrepreneur, private citizen on board of International Space Station) has drawn "Key lessons on the path from researcher to entrepreneur and beyond". G.Olsen founded Epitaxx (1984) and it was sold in 1990 (12$M). Then he founded Sensors Unlimited (1992) and sold it to Finisar for $600M in 2000 and bought back in 2002 for $6M and sold again to Goodrich Corp. for $60M in 2005. So G.Olsen concludes: timing is everything (sell in increasing time and buy in decreasing time), be ready and get a good price not the best. From his entrepreneur life, he learned some rules : Hire people who are better than you, Good managers work for their people not vice versa, bring on good people and let them take over and don't avoid mistakes but deal with them. He ended his talk with slides about his space story.

Guillermo (Gary) Tearney MD, PhD, Professor Harvard Medical School, heading lab at the Wellman Center (Massachusetts General Hospital) based on his own lab experience (first human imaging in the coronary arteries and GI tract in vivo both with OCT gave his talk "From academic innovation to biomedical application". G.Teaney explained that after time domain OCT, OFDI (optical frequency domain imaging) is 100 faster and allows to detect in 3D atheroma plaque and stent failure, and also used in GI to detect Barrett esophagus. Now much more is possible at micro level with spectrally encoded confocal microscopy (SECM) that does not require any high-speed scanning devices, yet is capable of obtaining cellular-level resolution images at hundreds of frames per second through an endoscope. The SECM team is also fabricating endoscopic probes and capsules capable of scanning entire luminal organs with this technology.

Micro-Optical Coherence Tomography (µOCT) is the highest resolution OCT technology available today. µOCT is being used in several areas in which its high resolution and speed make it the only technology able to image many biological phenomena. For example is in vascular disease, Intravascular ultrasound and conventional OCT can detect plaques in arteries, but µOCT can see the interaction between individual cells, helping to discover the factors that contribute to vulnerable plaque formation and rupture. In answering to question about reimbursement G.Tearney told us that it will take many millions dollars and years to prove the safety and benefit of OCT and Confocal technologies. Another questions was about 2 photons imaging, G.Tearney answered that is a nice features but needs to speed and to go to large scale, about CARS spectroscopy, it is complex and needs training and it is difficult to clinician to trust in it. Another progress is the combination OFDI

and NIRF to see the enzyme activity; it is the first coronary molecular imaging in vivo. Next steps should be nano OCT at nanoscale and STED endoscopy.

Stephen Aylward, PhD, founder and director of Kitware spoke about Open source software and benefit to use it during his talk “Improving patient care with open source software”. With ITK we can benefit of 1.5M code line (equivalent to 52 years of effort), we are on the shoulders of giants and we don’t reinvent the wheels. Open source is a conduit from academic to industry world. The impacts are reducing development cost, no recurring licenses, and you are focused on your applications, you own them and the hardware too.

A **panel discussion** about “The practitioner’s perspective” took place with John Frangioni, MD, PhD, Professor at Harvard Medical School and Physician at Beth Israel Deaconess Medical Center; Michael Dempsey, Entrepreneur in residence , CIMIT (Center for Integration of Medicine and Innovation Technology); J. Benjamin Crocker, MD, general internist and Medical Director of the Ambulatory Practice of the Future. Fabian D’Souza, MD, MBA, President of Boston Strategic Partners was the moderator.

Each panelist spoke about his experience and gave his advices, and main told things were: It is regrettable that primary care isn’t interesting for High Tech developers, because there is a need to reduce the clinical work flow. Partnership with clinician is a key for success. High Tech to become should imply doctors to allow getting 90% of market share. Mainly people are focused on technology, but should more talk to the buyers and users and integrate all the infos. Speak same language between R&D and clinician need collaboration instead of cooperation. No time for clinicians to be educated to technical aspects. It is important to be attentive to customer group and to include them in collaboration. Motivation to call on KOL services? : Not for promotion (difficulties to be honest), good high level publications (collaboration), KOL can help to find funding. Globalization to gain time?: reimbursements too different in many country, different healthcare systems, different clinical practice, so the advice is to go to known market, to have success on it and then go to global market. Academic testing? Academic testing is interesting but academic practices are different are not always clinical practice.

Fred Peyerl, PhD, MBA, Boston Strategic Partners, discussed the “Business modeling for disruptive developers”. He discussed the strategy and the business model, based on reflection about 3 items: Value creation, value delivery and value capture.

- Value creation : based on value proposition as newness, performance, customization, getting the job done, design, brand/status, price, cost reduction, risk reduction, accessibility… He illustrated it with 4 different products (biosimilar medicine, robotic surgery device, lasik device, low cost microscope). Second point is: For whom are we creating what value? He used Reteval (Visual electrodiagnostic device used for diabetic retinopathy) to underline which values are interesting for ophthalmologist, endocrinologist, GP and pharmacist.
- Value delivery: Value is less delivered by you, and more “accepted” by your customers. Success will come if you effectively reach your customers and convince them to buy. How to sell is depending on the kind of product. That can be done by your own or with partner, directly (sales force, web sales) or indirectly (own stores, partner stores, distributors).

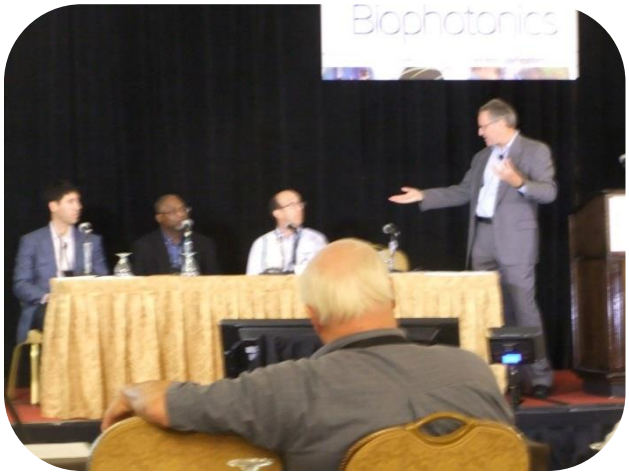
- Value capture: It is necessary to answer to questions as: For what value are our customers really willing to pay? For what do they currently pay? How do they currently pay? How much does each revenue stream contribute to overall revenues? The second point is: how do you intend to sell your product: asset sale, usage sale, subscription fees, lending/ renting/ leasing, licensing, brokerage fees? The type of pricing mechanism chosen can make a big difference in terms of revenues generated. Determining the optimal price is an iterative process taking into account: Competitive reference, price range the market is willing to pay and relative perceived value/ceiling.

Then there were 3 very interesting talks describing the Regulatory Affairs

"Regulatory pathway for Biophotonics-based system developers" by Sibyl Munson, PhD, Boston Strategic Partners. First of all you have to know which FDA center is applicable for your device, then you need to device classification procedure to determine the class of your product. S. Munson explained the difference between the 2 FDA approval : Pre-market notification (510K) or Pre-market Approval (PMA), roughly the first one is mainly used for Class II product (sometime Class I or III) and based on demonstration that your device is "substantially equivalent" in intended use, safety and effectiveness as a legally marketed "predicate device". If there is no legally marketed predicate device, PMA is required. PMA is required for class III product (high risk). PMA process is more involved and includes the submission of clinical data to support claims made for the device. S. Munson detailed the technical aspects of the PMA requirement. Don't forget the post market changes (device modification or unanticipated adverse effects, device failures…) requiring a PMA supplements. The different FDA fees were given and S. Munson concluded: "Don't let your regulatory strategy behind your technology development".

Fabian D'Souza, gave a talk "ABCs of reimbursement" and impact for Biophotonics market. This is a very complex system based on "3 party system" (Patient, Providers and insurance company or health agency). Health insurance can be provided by Medicare, Medicaid or private insurance. There is more than 100 private insurance. Reimbursement for healthcare goods and services comprises 3 issues: Coverage (local or national) Coding and cost. This is very different from European system.

Myron Greenspan, Attorney, Lackenbach Siegel LLP, presented "Patent and intellectual property issues for technology innovators". New status: "American Invents Act (AIA) signed into law in September 16, 2011. It applies to applications with priority claims that fall after March 2013. Changes should facilitate the ongoing harmonization with other country (Good thing for European companies). Main changes are: "First inventor to file system", changes on requirements for patentability, novelty and non obvious ness (based on effective file date or disclosure date not invention date as with prior law), new prior act definition. There is also a new post-grant review procedure: derivation proceeding and civil actions replaces interferences, Post-grant review > 9 months, Inter parties review replaces reexamination and rules pending.

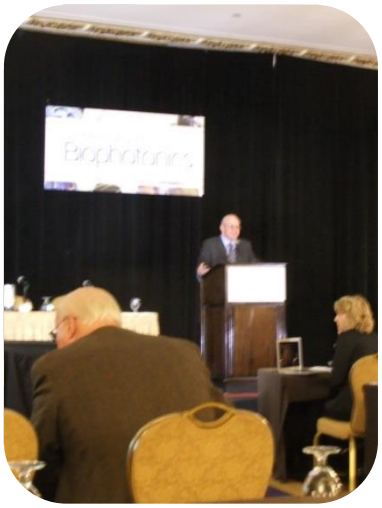


Round table about "Funding and acquisitions". Panelists are Richard Anders, executive Director, Mass Medical Angel, Ibraheem Badejo, PhD, Senior Director, New Ventures, J&J Innovation and David Hirsch Co-founder and Managing Director, Longitude Capital. Moderation is assumed by John Dexheimer, President, Lightwave Advisors.

Medical devices average deal declined to $3.5 M in 2013 versus $6 M in 2007. Funding from VC decreasing and now represent only 30% of the average funding of startup, on the reverse Business Angel fill the gap and their funding increase up to 40% in average.

R. Anders explained the importance of Business Angels at the early stage, they allow to share thing into group which collectively invest, they can go up to $4 M. J&J Innovation investments begin at $ 100 k and up to $ 7M and represent up to 20% at the funding. VC can take from 10 to 70% depending on the tactical of the funders. IP is important for investors, but so much for Business Angels. About the incubators (accelerator? Working with?), the most important is the combining expertise that can be found with (animal studies for example).

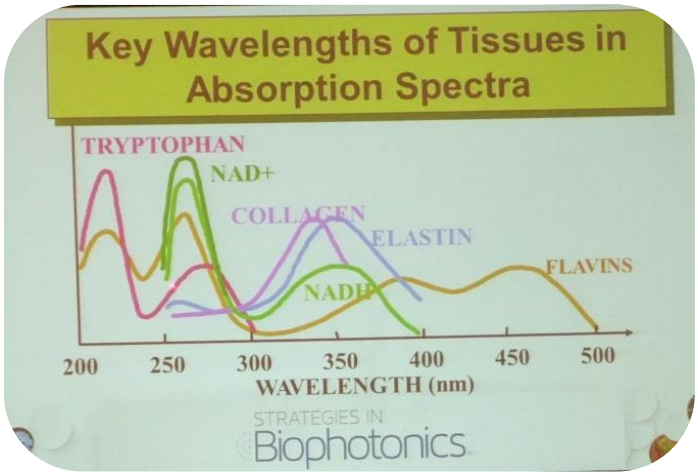
DAY 3 PRESENTATIONS SUMMARY



"Light based technology in aesthetic medicine: learning from successes and failures", Gregory Altshuler, PhD, DSc, Senior VP R&D, Dental Photonics. G. Altshuler has worked a long times with Palomar and developed a lot of laser devices for dermatology and aesthetic. Nearly all the Palomar products have been successful and a lot of them have been sold (for example: 12000 Lightsheer, a direct laser diode hair removal device, have been sold). Experience in home use device, hasn't been a success for Palomar, they developed FDA approved hair removal system for Gillette, but it has never been commercialized. They develop a fractional laser devices used for wrinkles reduction for J&J. The product got a great consumer satisfaction (4.5/5) the retail price is $ 500 but should be $ 300, and the CoG between $30 to $50. To sell it, they had great marketing expenses around $ 30M so to be profitable they have to sell more than 600 000 units! They failed. A future great market is the dental market, with new laser platform combining different wavelengths, normal or fractional laser. Implantology is a good market because the costs today are very high; another is tissue regeneration like in dermatology. On other side tattoo removal market is increasing and ps or fs laser will be soon on the market. What is important is improvement of treatment outcome, reducing cost for patients and doctors that mean low cost price and less treatment.

Robert Alfano, PhD, Distinguished Professor of Science and engineering, City College of the City University of New York, presented the recent advances in Optical biopsy spectroscopy during his talk "Light advances in biomediphotonics". He explained and detailed the new methods he used in biomedical optics:

- 3 new optical windows for deep imaging : The advance of InGaAs and InSb CCD/CMOS camera and supercontinuum as light source, made possible new optical windows : I- 1100 to 1350 nm, II- 1600 to 1870 nm, III- 2100 to 2300 nm. The scattering decreases from I to III and tissue becomes more glass-like.
- Using second singlet state (S2) from dyes for deep microscopic imaging: femtosecond laser at 800 nm is used in two photon excitation of S2 state and dye emits from S1 state. Optimizing both emission and absorption the emission should be in the therapeutic window (650 to 950 nm). For example with Chl a S2 state is excited by TPEF @ 800 nm and S1 emits @ 690nm.
- Tryptophan as key marker for cancer cells: Cells don't have collagen or elastin molecules, but have Tryptophan, NADH and FAD. There found more Tryptophan than NADH and FAD in breast and prostate cancer cells. So Tryptophan is a key marker for "aggressive" cancer.



Spatial frequency for cancer grading: The degree of randomness of tissue structure from normal to different stages of cervical neoplasia can be recognized by spatial frequency analysis obtained from optical Fourier transform.

R. Alfano concluded: The next step is commercialization of optical spectroscopy and photonics in medicine. New armamentarium will be added to current medicine tools using light and optical spectroscopy.

J. Frangioni represented his new startup company, Curadel, when he gave a talk about "Image-guided surgery and pathology using invisible NIR fluorescent light". Why using NIR light, because absorption, scatter and auto-fluorescence are minimum and it is invisible for human eye. Benefits are: High contrast, millimeter depth detection, no change to the look of the surgical field, any object can be potentially be highlighted, so it is possible to provide a real time intraoperative imaging. They developed a new class of Zwitterionic NIR fluorophores (315 compounds animal validated, 40 selected for their unique targeting ability) and they are developing the clinical product. They performed clinical trial using Methylene blue (fluorescence @ 700 nm) and Indocyanine green (fluorescence @ 800 nm) with FLARE device the first product from Curadel for research use only. FLARE means Fluorescence-Assisted Resection and Exploration. They used with good result from breast cancer sentinel lymph node mapping, breast tumor imaging for margins visualization, parathyroid tumor resection, vulvar and cervical cancer. The roadmap is FDA approval for next generation of contrast agent (won't peak for roughly 10 years); Expand clinical trials with MB and ICG; quantification of outcomes using "imperfect" agents MD and ICG. Then the surgery should be performed faster, better and/or cheaper using NIR fluorescence compared to standard of care. The benefits would be profound for the patients and the healthcare system.

Paul Hartung, President and CEO, Cognoptix Inc presented the "development of an innovative eye scanning system for the early detection of Alzheimer's disease". AD is characterized by Amyloid β plaque formation in the brain, but A β exist in the lens of the eye. Cognoptix devices are based on optical detection of the A β in the lens. They have developed specific ligand which has different fluorescence lifetime signature if it is bound or unbound to Aβ. The last devices Sapphire II using FLIM (Fluorescence Lifetime Imaging) has 85% sensitivity and 95% specificity (more specific than PET detection 80%). It is safe and a noninvasive PoC easy to use, with fast results and low cost (1/*10 of the current AD diagnostic process. It can detect AD at early stages and allows personalized track progression. Cognoptix has strong IP licensed by MGH, Brigham & Women's hospital and University of California San Diego and has been funded by 6 VC and Business Angels. Now they plan to begin multi-site Phase III (pivotal) clinical trial and they expect to be on US market in 2016. The 3 market sectors are office-based diagnostic ($2 B in US and advanced countries), AD screening ($10 B) and clinical trials for pharma AD drug ($ 150 M).

Next talk was given by Matthew Barre, MS, Business Development Manager, Daylight Solutions, about “Combining technologies to create a Mid-IR spectral imaging platform for biomedical research and instrumentation”. Combining IR spectroscopy and microscopy to probe molecular absorption, they obtain 2D images with IR spectrum at each pixel. This has been possible due to the development and integration of key components: high power, broadly tunable Quantum Cascade Laser, achromatic microscope objective with high N.A. and uncooled micro bolometer (480x480 pixels). Daylight solutions has been supported by SBIR I, II and IIB and SECO (cooperation with academic). The technology roadmap is: Research devices, niche clinical tool, High throughput and hand held probe.

The final talk was given by Aydogan Ozcan, PhD, UCLA Chancellor’s Professor, Associate Director, California NanoSystems Institute, Founder: Holomic. The subject was: “Democratization of next-generation imaging, diagnostics and measurement tools through computational photonics”. Based on observation that the mega-pixel count follows a Moore’s law, that the processor speed inside mobile phone is now at the PC level, that the average cost of data transmission over cellular network has decreased below to $0.05/Mbits and that cells phone are everywhere (7 billion are being used worldwide), there is a huge potential for new cellphone based platform for telemedicine. Some examples are: lens free microscope, fluorescent microscope, albumin tester, diagnostic test reader, blood analyzer… A.Oczan presented the LUCAS (lens less, Ultra wide field Cell monitoring Array platform based on shadow imaging). The LUCAS device (based on shadow imaging and incoherent holography) attached to a cell phone provides over 8 cm2 field of view with resolution of 40X objective microscope. This devices is lens-free (on-chip imaging), compact, cost effective, high throughput, highly sensitive, tolerant to misalignments and used LEDs. He showed impressive images of platelets, monocytes, lymphocytes and granulocytes with same quality obtained with 40X objective microscope. Cell counting in µfluidic channels are shown too. The Super resolution LUCAS is an improvement of the previous one, with a 24 mm^2 field of view and submicron resolution (300 nm). It consists of 23 LEDs, 23 optic fibers, 1 color filter, a CMOS sensor and a microcontroller, in a compact design (roughly 10 x 5 x 5 cm). Oczan detailed diagnostic test reader from HOLOMIC: an integrated rapid-diagnostic-test-reader platform on a cellphone, used for malaria, HIV… Big data also allows new opportunities in µanalysis, medical diagnostics and epidemiology. Using diagnostic test reader on cell phone + internet + powerful algorithm for big data management, diagnosis of malaria can be performing using a crowd-sourced games: BioGames. A. Oczan showed that non expert human crowd can collectively diagnose malaria infected cells. 95% sensitivity and specificity are obtained based on 20 gamers. Now more than 80 countries are playing BioGames with > 2.5 million cell diagnoses so far.

The last round table “**Disruptive innovation and the future of photonics-based medicine**” took place with G.Tearney, A. Oczan and Howard Shapiro, MD PC, Director for microbial cytometry as panelist and Daniel Gareau, PhD, as moderator. For A.O. the future is on mobile platform, for D.G. the future is disruptive technology with a high cost reduction. Business model is based first on developed countries and then emergent countries which used second hand smartphone. Obstacle is FDA versus product stability, new component required new FD approval. A.O. explained that wellness is not diagnostic so the devices don’t need FDA. H.S. oppose that diagnostic from cell phone based systems aren’t sure enough and lead to too much people for the next step of medical diagnostic, so the result is too much expense for the healthcare system. Then a hard and confuse controversy was engaged between A.O. and H.S. so not clear conclusion hasn’t been done.

EXHIBITION

An exhibition with 41 booths was organized as part of the conference. Exhibitors included **Avantes**, **IMT**, Nufern, **Edmund Optics**, BaySpec, **PI**, OFS, BW TEK, Princeton Instruments, Cambridge Technology, Laser Components, NKT, **Hamamatsu**, Optimax, **Cobolt**, Fianium, **Ocean Optics**… Each attendee had enough time to have profitable discussions on the booths and during the coffee breaks and lunch time.

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