Medical Packaging Challenges Tackled at IMAPS-UK "MedPack 2107" Workshop

The realities of introducing medical devices into the market were explored at the Medical Device Packaging Workshop organised by IMAPS-UK at the Trinity Centre, Cambridge on Thursday 18 May 2017. The workshop covered the state of the market for implementing digital healthcare in hospitals and the home, details of the new Medical Device regulations and an assortment of case studies were described to guide the attendees on the best practice, experience and pitfalls for gaining approval for new medical devices.

This workshop was attended by 32 people representing a broad spectrum of industrialist, academics, consultants and Research and Technology organisations.

The three main presentations in the morning covered the current market status of digital healthcare, an overview of "Lab on a Chip" developments and the regulatory requirements for approval of new medical devices.

Collette Johnson from Plextek presented "The Digital Market – A Healthcare Perspective" where the barriers to the implementation of digital health were explained, including:

- Lack of universal availability of reliable broadband and wireless systems
- Forthcoming changes in data protection laws
- Lack of training and education
- No confirmation of data collection
- Need for reliable data connection from wearable devices
- Patient acceptance of wearable devices

The factors that need to be considered for the successful exploitation in the digital healthcare market included:

- Development of sensors relevant to a particular disease or condition
- Design of products that cover a wide range of patient needs and user requirements
- Ease of integration into existing technologies and IT infrastructure
- Is it wearable without irritation and simple to use/maintain

Stewart Smith from the University of Edinburgh described "Sensor Technology – Lab on a Chip" gave a potted history of the development of "Lab on a Chip" concepts for diagnostics, sensing and DNA sequencing. He explained the principles of capillary and the methods by which small drops of liquid can be manipulated using techniques such as electro-wetting on dielectric (EWOD) and surface acoustic wave (SAW) to aid in the analysis of samples. He also demonstrated the principle of 3D printing of micro-fluidic channels with embedded electronics for optical sensing applications and the development of an "Organ on a Chip" approach for measurement of cell diseases and their growth.

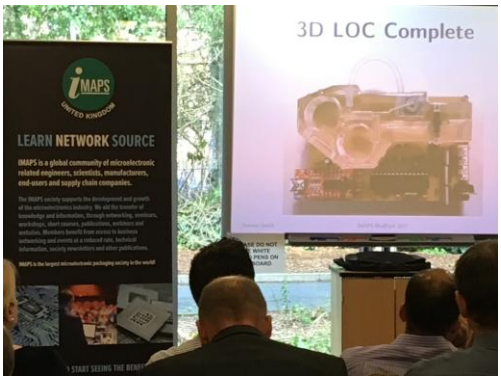
Thomas Beale from Newcastle upon Tyne Hospitals presented a comprehensive review of the current medical device regulatory requirements. A new Medical Device Regulation is coming into force in May 2017, covering the entire life cycle procedures for approving new medical devices. The review covered the Medical Device Classification, the many standards that apply to medical devices and the need for documentation including areas such as CE marking, technical documentation, clinical evaluation reports, clinical investigations and post market surveillance. He emphasised the need to talk to the regulatory bodies (MHRA, Notified Bodies and Clinical Engineering Departments) before embarking on the regulatory approval process for new medical device technologies.

The afternoon session presented a series of case studies over a wide range of topics:

An overview of Sonopil, an EPSRC funded project, was presented by Gerard Cummins of Heriot-Watt University. He described the development of a multi-sensor miniature capsule for endoscopy, with the aim of utilising video, thermal and ultrasonic imaging for non-invasive investigations. The challenges of miniaturisation, power budgets, battery life, mechanical robustness and hermeticity were highlighted, along with the need to locate the capsule accurately within the body.

Darren Wilson from Smith and Nephew traced the development of instrumented bone repair nails for load measurements in implants. The purpose of the instrument was to try to assess the healing of fractures, where, as the bone mends there is a reduction in load. This type of measurement can provide some quantitative data on the status of the healing process. On the packaging side, one of the main lessons learnt was that hermeticity was important and that silicone encapsulation did not provide the necessary protection, as it was difficult to flow into all the gaps in the instrumented nail. A welded solution gave the necessary hermeticity but was too costly to implement profitably. The end result of the development was to use the instrument as a smart probe assisting in surgical procedures.

Ewan Blair of the University of Edinburgh presented an overview of the IMPACT project (EPSRC funded), which described the packaging and sensor integration for implanted hypoxia monitoring in tumour after therapy. The aim of the project is to implant oxygen and pH sensors into cancerous tissue to measure cancer cell death. The connection to the sensors is achieved through a 2mm wide flexible printed circuit board (pcb) strip which can be inserted into the body. Successful insertion trials have been carried out on a sheep carcass, but the need for good adhesion between the encapsulating resin and the sensor chip was mentioned.



Abiodun Komolafe of Southampton University described an EPSRC project called FETT, where they are developing miniature electronics on thin circuit filaments with the aim of weaving the strips into yarn to be incorporated into textiles. They have successfully produced filaments containing LEDS/temperature sensors for oximetry measurement and accelerometers woven into garments. The main challenges of handling very small passive components/bare chips and the need for micro-encapsulation techniques were highlighted.

Sijung Hu of Loughborough University reported on the growth of wearable sensors for sports science, and in particular an optical sensor system for plethysmography, where the tissue is illuminated, there is light interaction with biological tissue and the light transmitted through the tissue is effectively captured. This system (named “Carelight”), which is produced as a patch for attachment to the skin, has shown promise for heart rate, blood pressure, body temperature and oxygen saturation monitoring in sports physiological monitoring. The main challenges of commercialisation of the device have included finding the right industrial partner and designing the system to be usable, disposable and have compatible processing and communication protocols.

The attendees also had the chance to network during the refreshment and lunch breaks. This workshop was very well received and acted as a forum for seeding future collaborations between industry and academia.

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Steve Riches
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