Seminar: Cleanroom Setting for Biomedical Engineering Application
By Mr Calvin WONG and Ms Crystal CHUI

Organized by the Hong Kong Productivity Council (HKPC) and supported by BM Division, the captioned seminar was held on 30 May 2014 at SME One of HKPC building. Presented by representatives from cleanroom contractor and medical device manufacturer, the seminar introduced the specialties of cleanroom design in medical device manufacturing procedures and the regulations governing cleanroom settings in the industry. Latest cleanroom technologies and facilities were also highlighted in the seminar.

The first speaker, Mr Calvin WONG, Engineer of Biomedical, Optical and Precision Engineering Unit of HKPC, shared his expertise on establishing quality management system (QMS) in medical device manufacturing industry. Calvin highlighted the major QMS compliance requirements for medical devices that required sterilization or high cleanliness controls. The standardization of cleanroom operation procedures including the materials in/out control procedures and performance validation procedures were also covered during the sharing.

The second speaker, Mr Adrian NG, Director of Airgate Engineering (HK) Limited, outlined the international standards for cleanroom classification, for example, ISO 14644 and ISPE SterileBaseline® Guide. Adrian clearly explained how cleanroom of different classes were defined in terms of particle size and particle number. By sharing the practical case studies on cleanroom establishment at medical device manufacturing sites, Adrian introduced the latest technologies for temperature control, humidity control, in-flow air sterilization and energy saving in cleanroom environment.

Lastly, Ms Ann YIM, Product Manager of Vincent Medical Manufacturing Company Limited, shared the outcomes of the cleanroom operation practices established in their company to fulfill ISO14644. Representing one of the leading local companies specialized in production of respiratory and orthopedics devices, Ann also suggested several major aspects that should be considered when a company is establishing its cleanroom for medical device production, for example, requirements on selecting suitable venue for cleanroom construction, designing air and water supply system and maintaining the cleanroom equipment.

This seminar covered the specific requirements in quality management system and the

design, installation and validation of cleanroom settings from the users' perspectives which highlighted the important elements the design, installation and management of cleanroom for medical device manufacturing.

(341words)

Speaker of the seminar: Mr Adrian NG, Director of Airgate Engineering (HK) Ltd.

Audiences enjoying the presentation of Ms Ann YIM, Product Manager of Vincent Medical Manufacturing Company Limited.