

**July 2007**

**Newsletter Membership  
Chair Message**



*Greetings from the Membership Chair!*

***SPECIAL EVENT FOR JULY 11<sup>TH</sup> AT GENENTECH!!!***

*We have a field trip to offer you.*

*July's ASQ Palomar section meeting will be held at the Genentech . (details inside). This meeting will consist of a facility tour followed by dinner at Genentech. The cost for this one-time event will be \$20. July 11<sup>th</sup> promises to be an excellent evening, so please register now.*

***About Genentech:***

*Considered the founder of the biotechnology industry, Genentech has been delivering on the promise biotechnology for more than 30 years, using human genetic information to discover, develop, commercialize and manufacture biotherapeutics that address significant unmet medical needs .*

*Today, Genentech is among the world's leading biotech companies, with multiple products on the market for serious or life-threatening medical conditions and over 50 projects in the pipeline. The company is the leading provider of anti-tumor therapeutics in the United States. With its strength in all areas of the drug development process — from research and development to manufacturing and commercialization — Genentech continues to transform innovative science into breakthrough therapies for patients.*

***MAKE PLANS, REGISTER, AND MARK YOUR CALENDARS NOW!***

*See you at the meeting.*

*Section 708 Membership Chair*

*Glen*

# The July Tech Clinic

**There will be no tech clinic for the July meeting**

***Tech clinic will resume in August.***

***INSTEAD, WE WILL BE CONDUCTING A FACILITY TOUR OF  
GENENTECH IN OCEANSIDE.***

## Education Chair Message

We plan to offer the following refresher courses this fall. Please let us know as soon as possible that you intend to enroll in one of the classes. We do need to meet the minimum enrollment for us to start the class. Please either email me or give me a call about your intention, or you know somebody who will interested in the class. I can be contacted at 858 683 0968, or email [shin@lynxsys.net](mailto:shin@lynxsys.net).

Course	Starting	duration	Meet	Location	Tuition	Text Book
CQI	7/17	12 wks	Tue	TBD	\$300	Quality Technician's Handbook/Griffth
CQA	8/16	14 wks	Thur	TBD	\$300	CQA Primer
CQE	8/01	18 wks	Wed	TBD	\$300	CQE Primer

Shin Ta Liu  
Education Chair, ASQ Section 708

### ***WANT AN EXTRA DOOR PRIZE TICKET***

**Just come to the meeting with the correct answer to the following Quality Question:**

***We will resume the door prize and book raffle at the August meeting.***

# The July Meeting

**On Wednesday, 11 July,**

***The ASQ Palomar section will be conducting a facility tour Genentech***

The Genentech Oceanside Campus is a multi-product, biotech manufacturing and clinical operations complex built on approximately 60 acres of land, containing six buildings and about 500,000 ft<sup>2</sup>. The Genentech Oceanside Campus has approximately 600 full time employees. The Manufacturing Building contains 3 Seed Trains, 6x16K liter Fermenters, 2 Harvest Tanks, and 1 Purification Suite and a shell for a second purification suite. The Manufacturing facility manufactures Avastin 1.2 which is approved, in combination with intravenous 5-fluorouracil-based (5-FU) chemotherapy, for first- or second-line treatment of patients with metastatic carcinoma of the colon or rectum and in combination with carboplatin and paclitaxel for the first-line treatment of patients with unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC). The Oceanside Quality Department consists of approximately 130 people. The Quality Control group is housed in about 100,000 sq ft of office and lab space, and is responsible for the analytical testing of the biopharmaceutical products manufactured by Genentech as well as analytical testing of the manufacturing facility and supporting utilities and raw materials. Quality Assurance offices are located mostly on the first floor of the Lab/Office building. QA has the ultimate responsibility to determine if products manufactured are safe and efficacious for administration to patients. They do so by reviewing all records and documentation associated with the facility, the manufacturing process, and testing to ensure that all was performed according to our license.

The Oceanside Process Development Group (OCN-PD) resides primarily in the Main Lab Office and Operations building with approximately 50 employees. OCN-PD comprises cell culture, purification, formulation and analytical development functions as well as a development pilot plant (capable of producing GLP materials for toxicology studies). OCN-PD primarily focuses on early stage clinical development projects, which are mainly therapeutic monoclonal antibodies for oncology and immunology applications. Every year OCN-PD works on 5 to 6 early stage projects. The processes developed by OCN-PD is transferred either to Oceanside's Clinical Plant or South San Francisco's Biochem for clinical manufacturing. OCN-PD is also chartered for technology innovation such as automation and high-throughput scale down systems.

The Oceanside Clinical Plant (OCP) is a single-scale, multi-product facility that resides on approximately 2.5 acres, and is equipped to produce IND Tox Phase I and II clinical bulk products. The 70,000 ft<sup>2</sup> plant consists of two (2) seed labs, one (1) INOC train, two (2) 2750L production bioreactors, one (1) purification train, warehouse, QC lab, and utilities. The plant is designed to be a low cost clinical manufacturing facility focused on speed to bulk and product to product flexibility. The Oceanside Clinical Plant has approximately 36 full-time employees.

**The plant address is: Genentech, One Antibody Way, Oceanside, CA 92056**

**See next page for the map to Genentech**

**Agenda:**

**5:30-6:00 Registration**

**6:00-7:00 Plant Tour**

**7:30-8:30 Dinner & Meeting**

**8:30 Adjourn**

**To ensure adequate food and seating, please make a reservation. Early reservation deadline is Noon on Friday, July 6. The dinner will be \$20.00 with early registration.**

**(visit <http://www.asqpalomar.org> for registration.)**

**The July meeting is by advance registration only.**

