# LAKE COUNTY BOARD OF HEALTH
# ADVISORY COMMITTEE APPLICATION

Debra DePauw — 847-249-5091

**Name** — **Home Phone**

242 Pilgrims Path — Gurnee

**Home Address** — **City**

IL — 60031 — Lake

**State** — **Zip** — **County**

Independent Consultant

**Place of Employment** — **Title**

**Address** — **City**

**State** — **Zip** — **County**

~~Business~~ Cell Phone

debradepauw@aol.com

**Email Address(es)**

**Community activities, including offices held:**

Treasurer of Secretary for Providence Village Homeowners Association, Member of the Community Health Advisory Committee

**Professional Activities/Organizations, including offices held:**

member of Society of Quality Assurance

**I am interested in the following committee(s):**

EHAC

**Please state why you are interested in the appointment:**

I would like to be involved in community health activities.

**References:**

| | |
|---|---|
| **Name** | **Name** |
| **Affiliation** | **Affiliation** |
| **Address** | **Address** |
| **Phone** | **Phone** |

**If nominated, nominated by:**

**Name**

**Affiliation**

**Address**

**Phone**

**Committee membership is open to providers, consumers and citizens from Lake County. This ensures a balance of input from all groups affected by and interested in Lake County Health Department activities. At times, it is necessary to identify potential conflict of interest situations; therefore, please answer the following question.**

**Currently, or within the last 12 months, have you had any ownership, employment, medical staff, fiduciary, contractual, creditor, consultive, or familial relationship with the Lake County Board of Health, Health Department, or with any of its employees?**

☐ **Yes** ☒ **No**

**If Yes, please explain:**

**Each new applicant for membership is requested to complete this form. Present Committee members shall annually update the information. Each member is also responsible for notifying the Health Department of any change in employment or affiliation.**

**Attach a resume, if available.**

**The above information is accurate and correct to the best of my knowledge.**

Dek DePaw
Signature of Applicant

21 Nov 2016
Date

# DEBRA DePAUW

242 Pilgrims Path
Gurnee, IL 60031

847-644-3895
debradepauw@aol.com


## EXECUTIVE SUMMARY


Registered Nurse and Good Clinical Practice (GCP) Registered Quality Assurance Professional (RQAP-GCP), with comprehensive experience in clinical research in the pharmaceutical industry for over twenty-four years. Extensive knowledge of clinical quality assurance and adverse event reporting requirements and SAE narrative writing. Proficient in managing clinical adverse event data, clinical study data review, GCP training, and writing; including clinical, technical, standard operating procedures (SOPs), metric analysis, and trending.


## PROFESSIONAL EXPERIENCE

**INDEPENDENT CONSULTANT (GCP)** **2012 to present**

- Clinical Quality Assurance Audits and Gap Analyses (e.g. Clinical Study Reports, Integrated Summary of Safety, Integrated Summary of Efficacy, Pharmacovigilance, etc.).
- Writing (e.g. SAE narratives, SOPs, clinical documents, technical documents, etc.).
- Medical and safety review of clinical study data.
- MedDRA coding review and Anatomical Therapeutic Chemical (ATC) drug classification review.
- Serious adverse event reconciliation.
- GCP training.

**BIOSANTE PHARMACEUTICALS, INC. Lincolnshire, IL** **2010 to 2012**
***Clinical Trial Safety Manager***

- Wrote and reviewed serious adverse event narratives.
- Reviewed clinical data to identify potential safety concerns.
- Generated medical safety-related queries, and managed the queries to resolution in collaboration with investigative sites, monitors, and data management.
- Reviewed MedDRA coding of adverse events and medical history for accuracy and consistency.
- Participated in revising coding conventions in collaboration with clinical operations and data management.
- Provided training on the medical safety query process and quality assurance - internally and externally.

**TAKEDA GLOBAL RESEARCH & DEVELOPMENT CENTER, INC., Deerfield, IL** **2008-2010**
**Clinical Quality Assurance (CQA) Audit Response Project Manager** **2005-2008**

- Produced quarterly CQA audit observation trend reports, categorizing audit observation finding trends used for risk analysis and corrective action planning and implementation by Takeda Clinical Operations.
- Developed and conducted training on constructing quality CQA audit observation responses.
- Contributed to redesign and validation of an upgrade of the Takeda Global and Research Development (TGRD) US & EU quality assurance audit database.
- Authored a user manual for the TGRD quality assurance audit database as part of the upgrade.

**TAP PHARMACEUTICAL PRODUCTS, INC. Lake Forest, IL** **1995-2008**
**Research Quality Assurance (RQA) Audit Response Manager** **2005-2008**

- Evaluated, and tracked to closure, audit observation responses and corrective actions for all GLP and GCP audits (approximately 50-100 audits per year).
- Produced quarterly RQA audit observation trend reports, categorizing audit observation finding trends used for risk analysis and corrective action plans and implementation within TAP R&D.
- Developed and conducted training for R&D personnel on constructing quality audit observation responses.
- Contributed to redesign and validation of an upgrade of the TAP quality assurance audit database.
- Presented FDA, RQA, and industry compliance trend information quarterly to TAP Executive Management for risk assessment and quality management.
- Audited an average of four clinical documents per year for submission to the FDA.

**Research Quality Assurance Associate Project Manager** **2004-2005**

- Assisted RQA managers with development of audit plans and document collection for conducting audits.
- Assisted the RQA Audit Response Program Manager with audit observation response management.

**Pharmacovigilance (PV) Project Coordinator** **1999-2004**

- Reviewed clinical safety data for TAP studies weekly to assure adverse event data was being reported on a timely basis according to FDA regulations.
- Wrote SAE narratives and reviewed safety sections in clinical study reports, IND annual reports, investigator brochures, and sNDAs for submission to the FDA.
- Assisted in the daily collection, investigation and processing of serious adverse events for TAP's investigational drugs for reporting to the regulatory authorities according to their regulations.
- Developed and presented much of the internal department technical database training, as well as the safety data reporting training to TAP Clinical Operations personnel.
- Developed and copresented the safety data portion of the "Laws, Regulations and Guidelines" training presented to all TAP R&D personnel.
- Created and revised PV SOPs; keeping up with departmental changes and FDA regulatory changes.

**Senior Medical Services Specialist** **1995-1999**

- Investigated reports of serious adverse events for TAP's marketed and investigational drugs for reporting to the FDA and prepared the documentation required to meet FDA regulations for expedited reporting of serious adverse events and periodic safety data reporting.
- Addressed and documented an average of thirty phone calls per day, according to FDA regulations, from consumers and healthcare professionals regarding one of TAP's marketed products.

**ABBOTT LABORATORIES, Abbott, Park, IL**
**Clinical Research Coordinator** **1992-1995**

- Coordinated clinical activities for pharmaceutical studies on a 50-bed Phase 1 unit.
- Supervised a staff of twenty full-time and contractual employees; managing and completing fifty-nine phase 1 clinical studies in less than three years.
- Assisted with phase 1 study design, execution and formal documentation for all studies conducted.
- Controlled research materials and biological samples for all studies conducted.

**The Nursing Spectrum magazine, Wauconda, IL**
**Writer / Proofer** **1991-1992**

- Edited manuscripts and news releases and proofread articles and advertisements for conciseness and accuracy for biweekly publication.
- Wrote numerous short and lead feature articles including, "Advice Nursing", January, 1992 and "Dealing with Children in Emergency Situations", July 1992.

**CONDELL ACUTE CARE CENTER, Vernon Hills, IL**
**Staff Nurse** **1989-1999**

- Triaged non-scheduled patients and managed workflow of doctors and staff at a busy drop-in clinic (an average of twenty patients in an 8 hour shift).
- Coordinated and participated in approximately 12 "Teddy Bear" clinics per year (child outreach program).
- Facilitated quality assurance program for the center for last two years of employment.

**KAISER-PERMANENTE, Martinez, CA**
**Advice Nurse / Relief Chemotherapy Nurse** **1983-1988**

- Triaged an average of sixty phone calls per day to prioritize treatment for clients calling with questions about pediatric, medical/surgical, orthopedic, dermatologic, OB/GYN, ENT, ophthalmologic and miscellaneous problems.
- Developed, authored, and implemented approximately fifty Advice Nurse protocols that provided clients with medical advice.
- Evaluated performance issues of employees as a member of the Professional Performance Committee.
- Managed chemotherapy patient scheduling and administered chemotherapy to cancer patients in busy outpatient oncology clinic when the regular Outpatient Chemotherapy Nurse was out of the clinic.
- Instructed patients on what to expect with chemotherapy prior to starting treatment.
- Developed and presented C.E.U. course for hospital staff nurses on "Advice for Cancer and Chemotherapy Patients" to improve their understanding of how best to care for chemotherapy patients.

**COLUMBIA & ELMBROOK HOSPITALS, WI** **1977-1983**
**Medical / Surgical Nurse, ICU / CCU Nurse, Infusion Therapist**
PM shift team leader on busy forty-five bed Medical/Surgical unit. Administered inpatient and outpatient intravenous therapy and chemotherapy in a 500-bed hospital. Taught patients home intravenous infusion procedures. Provided critically ill patients with specialized nursing care in a 10-bed ICU/CCU unit.

## EDUCATION

**Bachelor of Science, Sociology and Health Studies** **Barat College, Lake Forest, IL**

**Diploma in Nursing** **Columbia Hospital School of Nursing, Milwaukee, WI**

**Course work in Quality Assurance and Project Management at Keller Graduate School of Management of DeVry University, IL**

## PROFESSIONAL AFFILIATIONS/CERTIFICATIONS

GCP Registered Quality Assurance Professional (RQAP-GCP)
Member of Society of Quality Assurance (SQA)
Certificate of Professional Education in Dementia Assessment, Care and Management in June 2010