#### Curriculum vitae

## Louis J. DeFilippi, Ph.D. President, Louis DeFilippi LLC Founded July 29, 1999

## **Independent Consulting since October 1995**

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# TECHNICAL ACCOMPLISHMENTS & EXPERIENCE Expert Consulting

#### EXECUTIVE SUMMARY

Senior consultant, domestic and international, in the following major areas:

- 1. Classical chemistry and biochemistry, especially the separation, purification, characterization and analysis of small molecules, enzymes and proteins and related processes. Adept at assessing and evaluating current processes and procedures!
- 2. Chemical and biochemical processes, their development, evaluation, optimization, including biocatalysis (enzymatic and microbial) and applied biotechnology
  - 3. Environmental science, especially bioremediation
  - 4. Microbiology & fermentation science
  - Regulatory compliance (OSHA, EPA, Groundwater, USDA, Homeland Security, etc.)
  - 6. Expert witness & consultant; patent infringement, claim construction, trade secrets,

# LABORATORY AND APPLIED BIOCHEMISTRY & CHEMISTRY: PROCESSES, ANALYSIS AND SEPARATIONS SCIENCE:

Broad experience and understanding of physical, chemical and biochemical processes and related analytical methods (assay development) and: spectroscopy, electrophoretic and chromatographic separations, protein modification, ligand binding, enzyme assay and kinetics, thermodynamic calculations etc.

- Analytical chemistry, bioassays and separations science (especially chromatography, liquid-liquid extractions, countercurrent separations; electrophoresis)
- Biochemistry and biophysics combined with physical chemistry, especially through the use of UV/Vis (Ultraviolet / Visible) Spectrophotometry
- Separations technology for purification and analysis of numerous small molecules, proteins, peptides, carbohydrates, and natural products used in commercial applications



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- Small molecule binding studies, ligands, inhibitors especially involving enzymes
  - Adsorbents, ion exchange and activated carbon
  - Separations science experience includes extensive application of:
    - Chromatographic separations
      - DEAE cellulose
      - > CM cellulose
      - ➤ DEAE Sephadex
      - CM Sephadex
      - Hydrophobic interaction chromatography (HIC)
      - Sepharose
      - > Size exclusion
    - Electrophoresis
      - > PAGE
      - > SDS
      - Cellulose acetate
    - Membrane separations
      - ➤ Reverse Osmosis
      - ➤ Ultrafiltration
      - Microfiltration
    - Liquid/liquid, Liquid/solid separations
    - Precipitation using...
      - > Chaotropic agents (altering solubility, salting out, precipitations)
      - > Salts
      - Organic solvents

#### PROCESS EVALUATION

 Adept at evaluating current processes at customer facilities in the Chemical, Biochemical, Microbiological and Food industries and suggested improvements to increase efficiency and reduce costs.

#### **CHEMISTRY and BIOTECHNOLOGY**

Expert in applied industrial chemistry, enzymology, biocatalysis, biotransformations & bioprocessing, especially low-waste "green" systems and thermostable enzymes; emphasis on practical aspects of research, development, scale-up, pilot plant and commercialization. Adept at working with both laboratory personnel & development engineers; hands on when needed.

- <u>Applied enzymology</u>: Marriage of organic chemistry and enzymology... use of enzymes to make products in high yield with little waste (see examples below).
- <u>Industrial enzyme projects include mostly "green" and thermostable industrial processes:</u> Expert in continuous, heterogeneous biologically catalyzed processes (immobilized enzymes and immobilized whole cells).
  - Preparation and application of immobilized whole cell hydantoinase suite of enzymes for industrial biotransformation process for production of enantiomerically-pure amino acids
  - Pilot-scale immobilization of pig liver esterase for production of anti-AIDS drug and subsequent project management for scale-up
  - Employing a statistical DOE approach for optimizing coupling of a peptide with a microbial polysaccharide for commercial vaccine production (Tetanus Toxoid); optimization of conditions for efficient coupling of enzyme to chemically-modified polymer surface



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- Optimization of ethanol precipitation of plasma proteins for industrial plasma fractionation
- Acetone precipitation and purification of proteins
- Use of salts for commercial enzyme/protein purification
- Development and testing of novel hydrophobic enzyme support for industrial lipase, esterase application in production of pharmaceuticals
- Fermentation, E. coli producer strain, optimization of cell yield
- Immobilization and application of genetically modified Pseudomonas sp lipase for enantioselective hydrolysis of pharmaceutical intermediates
- Research and commercial development of novel, incompressible, high-throughput immobilized enzymes (food industry).
- o Invention, application, and development of new method for enzyme stabilization
- o Invention of novel magnetic support for enzyme immobilization
- Commercial application of thermodynamics of activation vs. deactivation (Arrhenius plot) to increase industrial enzyme process efficiency by 20-30%
- Other industrial bioprocessing, enzyme transformation and biochemical projects include:
  - Purification, characterization and application of numerous enzymes, especially with metal or metalloid cofactors, including:
    - Carbonic anhydrase (zinc; for CO<sub>2</sub> sequestration)
    - Superoxide dismutase (copper / zinc; superoxide destruction)
    - ➤ Horseradish peroxidase (iron heme; enzyme stabilization; generation of oxidants)
    - Catalase (iron heme; peroxide catalysis)
    - ➤ Hemoglobin (iron heme; oxygen transfer)
    - Glutathione peroxidase (selenium)
  - Carbohydrate conversions (see food section)
  - Chemical modification of hydrocolloids for metal binding application (food and environmental applications)
  - Hydrocolloids for enzyme immobilization (food application)
  - Lipases for making synthetic cocoa butter
  - Lipases (esp. Cal B, thermostable) for mono- di- and triglyceride production and transesterification; value added products (especially involving ferulic acid, soy/soya lipids/oil, fish oil)
  - Lactase /protease combination employed for whey treatment
  - Yeast alcohol oxidase for methanol oxidation
  - Glucose oxidase for production of D-glucono-δ-lactone
  - O Glutaraldehyde as sterilant for food applications
  - Biochemical fuel cell
  - o Microbiology, especially fermentative production of enzymes

#### Medical and Pharmaceutical:

- Use of applied enzymology for the production of pharmaceutical intermediates;
- Patent holder, peptide-based anti-microbial pharmaceuticals employed in wound dressing applications.
- Small molecule protection against reperfusion injury (ischemic stroke and heart attack) and anti-inflammatory effects of riboflavin (vitamin b2)
- o Small molecules and metals to enhance would healing rates

#### ENVIRONMENTAL BIOTECHNOLOGY, INDUSTRIAL EFFLUENT PRETREATMENT, BIOREMEDIATION AND EMISSIONS TREATMENT

• Nationally-recognized consultant in <u>biological and chemical treatment</u> of air pollutants, hazardous waste, hazardous chemicals, water pollution, drinking/potable water



- Inventor of <u>Biological Air Treater (BAT)</u> for low-cost transfer of gases / vaporous organics (air pollutants) from air phase to water phase and subsequent biocatalytic transformations (patented/commercial)
- Microbial ecology approach to waste treatment and bioremediation
- Extensive field experience... pilot plant direction, data analysis, scale-up estimation, commercialization; patent holder, biologically-based reactor development and commercialization (especially fixed-film reactors)
- Developed structured adsorbent used as <u>microbial support in bioremediation</u> of industrial effluent, groundwater and vaporous (air) emissions (patented/commercial)
- Developed mixed media employed as plugging-free <u>microbial support</u> in bioreactor packing (patented/commercial)
- Developed *in situ-ex situ* bioremediation method for <u>detoxification of metals</u>, especially hexavalent chromium, Cr(VI), by combining inorganic chemistry and microbial ecology (sulfate reducing bacterial consortia); patented
- Chemically modified natural polymers for use as <u>heavy metal</u> adsorbers.
- On-Site international experience (China [PRC], Taiwan [ROC], UK)
- Designed and implemented numerous <u>waste treatment and remediation strategies</u> for diverse industrial effluents, impacted groundwaters, drinking water, soils, and air emissions
- Supervised replacement of PCB (polychlorinated Biphenyl) -Transformer and replaced with non-toxic, biodegradable electrolyte-containing transformer

#### FOOD AND NUTRITIONAL SUPPLEMENTS

- Carbohydrate transforming enzymes, esp. glucoamylase, alpha amylase, glucose isomerase
- Fish oil and Omega-3 fatty acids

#### **FOOD SAFETY AND FDA**

- Food storage and handling
- Odor reduction and sanitation using chlorinated chemicals
- HACCP plans (Hazard Analysis and Critical Control Point) and process flow charts, especially for ready to eat foods
- SSOP (Sanitation Standard Operating Procedures); Regulatory requirements under the federal meat inspection act and the poultry products inspection act, especially 9cfr PART 416—SANITATION)

#### **REGULATORY, OSHA & EPA**

- Multiple private consulting projects to achieve compliance with <u>Federal & State regulations</u>, including
  - ⇒ OSHA 1910.119, Process Safety Management (PSM)
  - ⇒ EPA 112r, Risk Management Planning (RMP);
  - ⇒ SARA Title III Emergency Planning and Community Right to Know Act (EPCRA);
  - ⇒ Storm Water Pollution Prevention Plans (SWPPP).
- Drinking water standards

# TECHNICAL MARKETING, SALES, MANAGERIAL & BUSINESS ACCOMPLISHMENTS & EXPERIENCE





- Experienced in all phases of commercialization business, from research to development to marketing and sales:
- Successfully commercialized laboratory scale reactor (biological waste treatment) through rapid development phase into commercial product; business profitable at 13 months; ten-fold increase in sales.
- Account manager, proposal generation, expert in managing numerous \$100K to \$1000K projects from conception to commercialization.
- Budgetary estimation.
- Technical sales presentations directly to customers; responsible for visiting outside customers to determine their actual needs and then partnering/ bridging with internal experts to achieve technical and commercial goals.
- Technical marketing and sales, environmental area.
- Excellent communication skills.
- Professional recruiting (fourteen years).
- Long-term experience in TQ approach to solving cross-disciplinary problems with teams of 2 to 10 individuals, on and off site.

#### **EXPERT WITNESS and PATENT INFRINGEMENT**

- Experienced (defendant and plaintiff)
  - Insurance investigations
  - Expert witness
  - Deposition
  - o Evidentiary hearing
  - Preparation for trial
  - o Patent infringement, claim construction, trade secrets
  - o Litigation-related experience supplied upon request

#### **EDUCATION**

- **Postdoctoral Fellow** under Prof. Quentin H. Gibson, Cornell University, 7/76 7/78.
- **Postdoctoral Fellow** under Prof. Donald E. Hultquist, The University of Michigan, 1/76 6/76.
- **Ph.D.**, Biological Chemistry, The University of Michigan, 9/71 1/76.
- **BA**, Chemistry (Honors), Queens College, The City University of New York 5/71.

#### SELECT TRAINING/DEVELOPMENT/PRESENTATIONS

- HAZWOPPER Emergency response Refresher Training (40 hour initial training, 8 hour Haz. Waste Operations Management continuing yearly), 1991 to Current (1995).
- Emergency Notification Release Reporting Training, EPCRA 304; CERCLA 103 (EPA Region 5), 1999
- Risk Management Program Assistance (IEMA), 1999
- Basic Ammonia Refrigeration, 1998
- Statistical Design of Experiments (DOE), 1996
- Scorecard Training, 1996



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# DOCKET

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