

Delphi Consulting Group

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CONSULTING TERMS AND FEES

Regulatory consulting services from Delphi Consulting Group (DCG), is provided to clients under the following conditions and terms:

- DCG personnel act as an independent consultant and not as an agent or employee of client i.e., IRS 1099. DCG shall be responsible for all taxes as an independent consultant.
- DCG shall have no authority to bind client or incur obligations on behalf of client except when specified in a signed contract agreement.
- A signed, dated agreement of confidentiality and consulting agreement between client and DCG shall precede any services.
- All produced document(s) are provided without copyright in Word (doc or docx), and / or OpenOffice (doc or odt) file formats in Windows OS as selected by client. Some files shall be provided in PDF format. All supplied Federal Government data / documents provided “as is.”
- Office supplies, documents copies and shipping costs billed at cost.

Detailed Breakdown of Fee Structure

Fees determined by quotation, fixed price, or person-day bases. Each client’s regulatory needs are unique and thus require a complete review for an acceptable and proper Consulting Agreement and Statement of Work (SoW), and Cost Quotation.

Established DCG hourly fee rates for services are as follows:

- Regulatory, Submission work, and teleconferences are \$85.00 hour US, billed in half hour increments.

The above rate includes normal office supplies, computer services and / or any taxes. All non-labor services billed without markup. Time billed in half-hour increments. Document Copies, binders, and other expenses required when submissions are sent to the FDA are billed at cost. ¹

¹ Invoices are mailed at the end of each month. Payment is due 10 days from Invoice date.

Estimated costs of common tasks

The following provided for budget estimates only. Each task requires an analysis to determine true DCG costs or estimated costs. Fixed price, turnkey contract(s) possible for common tasks. All estimates shown are based on **NO** travel. DCG utilizes the Internet to reduce travel and travel costs to zero. Contact DCG for information regarding teleconferences, and / or videoconferences.

Traditional 510(k) submissions preparations, less testing, FDA User Fees and / or 3party review and validations costs are:

- | | |
|--|----------------------|
| ➤ Non-powered disposable device | \$5,000 to >\$10,000 |
| ➤ Non-powered disposable device – sterilized | \$7,000to >\$10,000 |
| ➤ Non-powered implanted | \$8,000 to > ~ |
| ➤ Powered, non-wireless, w/o sterilization | \$8,000 to >\$10,000 |
| ➤ Powered, wireless with/without sterilization | \$10,000 to >15,000 |

FDA and/or Third Party Review Fees

Note: These fees are fixed each fiscal year.

The FDA User Fee review fee schedule for government fiscal year 2011, (Oct 2010 through Sep 2011) is:

- | | |
|-------------------------------------|-------------|
| ➤ 510(k) Standard (full) fee | \$4,348 |
| ➤ 510(k) Small Business* | \$2,174 |
| ➤ 513g Standard (full) fee | \$3,190 |
| ➤ 513g Small Business | \$1,595 |
| ➤ Yearly Establishment Registration | \$2,179 |
| ➤ PMA / IDE | Contact DCG |

- Note: To secure Small Business Certification company financial data must be provided to the FDA. Standard (full) fee payment does not require any financial data to be provided. FDA User Fees increase with each new fiscal year.

Common **Third Party review fees** range between \$4,700 to > \$10,000. When Third Party review is utilized the FDA fee is not paid. Thirty party reviews must be completed within 30 days if without questions or submission deficiencies.

PreIDE meeting request does not have a fee. PreIDE requests do not have a reply time limitation.

Testing Costs – Typical

The following provided for **budget estimates only**. Each task requires an analysis to determine true testing costs or estimated costs.

- Safety Testing electro/mechanical device – range between \$ 8,500 to \$20,000
- EMI Testing – range between \$7,000 to \$15,000
- Bio and Toxic – range between \$10,000 to \$30,000
- Sterilization Validation – range between \$ 6,000 to \$20,000
- Bench Testing – range \$3,000 to A/R, very device dependent
- Software Validation – range \$ 5,000 to \$25,000
- Small clinical study – range between \$ 100,000 to \$ 500,000

Disclaimer

DCG and contracted firms will make good faith effort to meet all current and established regulations, laws, and guidelines in the production of supplied documentation and counsel. However, the interpretation of regulations often is subject to individual understanding, thus, DCG cannot guarantee that another agency or person will reach the same conclusions in each case.

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Each DCG contract shall contain a client cancellation cost. This cancellation cost shall be based on the complexity and percent of completion of the task.