

Delphi Consulting Group (DCG)

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DCG is a boutique US FDA regulatory assistance firm serving worldwide medical device manufactures with product release in the US and Canadian market. With the following services; Good Manufacturing Practices [GMPs],¹ documentation, acting as US Agent,² and other FDA and Health Canada interface requirements. Our small size and low overhead costs allow us to provide prompt response to needs, with equitable overall costs. DCG's client base is worldwide. DCG works to make all tasks and task costs as transparent as possible.

Consulting Terms and Fees

Consulting services from Delphi Consulting Group (DCG) are 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 and dated contract agreement.
- A signed, dated agreement of confidentiality and consulting agreement between client and DCG shall precede any services.
- All produced document are provided without copyright in Word (doc or docx), WordPerfect, TextMaker and/or LibreWriter file formats in Windows as selected by client. All files are stored in DropBox folders with 'Shared.' All supplied Federal Government data/documents provided "as is."

Detailed Breakdown of DCG Fee Structure

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

Task Description	Hourly Billing Rate	Comments
General Regulatory/Submissions	\$85.00 US	All general regulatory tasks. Used as a billing rate for Not to Exceed Cost Quotations. Time billed in fifteen minute increments.

¹ Good Manufacturing Practices are custom edited for a given business, contact DCG for cost.

² US Agent costs are determined by the number of products covered.

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Task Description	Hourly Billing Rate	Comments
E-mails requesting information and require re-search	\$85.00 US	Billing maybe accumulated for the month or billed as running time.
Teleconferences when DCG is the host	\$85.00 US	Billed as true running time in one minute increments. DCG utilizes Skype, or Zoom*, for host.
Teleconferences as participant only	\$45.00 US	Billed as true running time in one minute increments.
Not to Exceed Cost Quotations	As quoted	Applies only to submissions with established FDA process does not consider extra tasks.
Client Retainer Contracts	As quoted	This style of contract can be advantageous for clients with defined needs on going.

43 * Preferred.

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45 The above rates include normal office supplies and computer services. All non-labor services billed
46 without mark up. Time billed in quarter-hour increments. Document Copies, binders, FedEx, and
47 other expenses required when submission are sent to the FDA are billed at cost. DCG accepts pay-
48 ment via US based checks, and/or wire transfer (preferred). DCG does not accept payment via
49 Cryptocurrency.

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Estimated costs of common tasks

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53 **The following is provided for budget estimates only.** Each task requires an analysis to determine
54 true DCG costs or estimated costs. Fixed price, turnkey contract(s) possible for common devices. All
55 estimates shown are based on **no** travel. DCG utilizes the Internet to reduce travel to zero. After 30
56 years of submission experience DCG does not believe any travel is required to provide successful
57 FDA release to market for any device. There are reasons why FDA Meetings should be of the Tele-
58 conference type rather than 'face-to-face.'³ This is a real cost saving to client.

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Costs - Typical - Safety Testing and Submission

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62 The following provided for **budget estimates only.** Each task requires an analysis to determine
63 true testing costs or estimated costs. Fixed price contract possible for common devices from some
64 testing companies.

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Safety Testing [General]

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DCG Does not conduct any testing.

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The below Estimated costs are based on
68 past history costs from Certified Testing Companies.

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Safety Testing electro/mechanical device – ranges between \$ 8,500 to \$ 20,000

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EMI Testing – range between \$ 7,000 and \$ 15,000

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Bio and Toxic – range between \$ 8,000 to >\$ 25,000

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Sterilization Validation – range between \$ 4,000 to >\$ 9,000

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Bench Testing – range between \$ 3,000 to A/R, very device dependent

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³ Call DCG (+832-675-9281) for a full explanation of this.

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DCG Estimated Submission Preparation and Monitoring of FDA Review Billing costs

Traditional 510(k) submissions, less testing, FDA and/or 3 party review and validation costs.
Non-powered disposable device..... \$ 5,000 to >\$ 10,500
Non-powered disposable device – sterilized. \$ 6,000 to >\$ 12,500
Non-powered implanted \$ 7,000 to \$ A/R
Powered, non-wireless, w/o sterilization needs. \$ 6,000 to >\$ 12,500
Powered, wireless with/without sterilization needs. \$ 6,500 to >\$ 15,500

Small Business Certification

Web page for filing for Small Business Certification: <https://www.fda.gov/media/93354/download> copy and paste. Small Business Certification reduces the US FDA User Fees. Payment of US FDA User Fees is the responsibility of the client. These fees must be paid in full when the submission is sent to the FDA for review.

FDA Small Business Certification is free and requires an annual renew.

Disclaimer

DCG and contracted firms will make a good-faith effort to meet all current and established regulations, laws, and guidelines for 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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FDA release to market submission do not contain any travel or travel cost, as it simply is not needed.

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.

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